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(54) **PROSTHETIC HEART VALVE HAVING TUBULAR SEAL**

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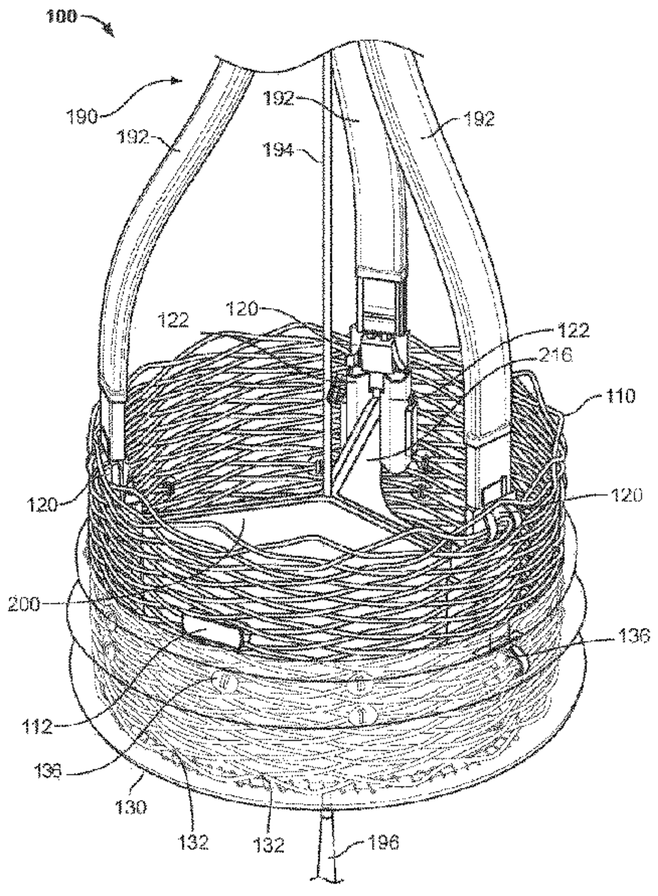
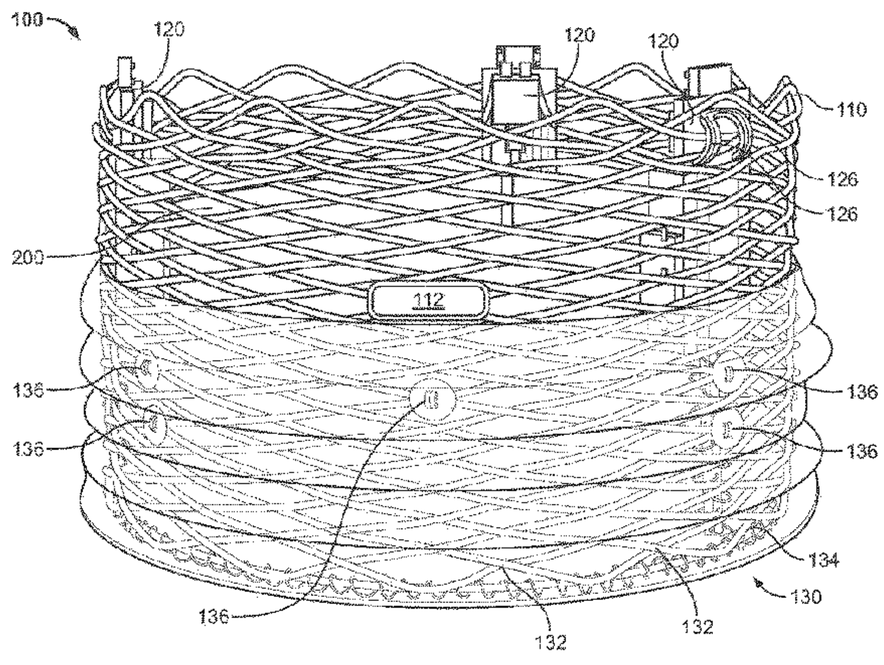
(57) **ABSTRACT**

A prosthetic heart valve includes a plurality of leaflets and an expandable member including one or more braided wires with a first set of wire segments extended helically in a first direction and a second set of wire segments extended helically in a second direction such that each wire segment of the first set intersects a plurality of wire segments from the second set at a plurality of intersection points. The one or more braided wires can have crowns where the wire segments of the first set connect to wire segments of the second set. The heart valve can include a tubular seal secured to the plurality of leaflets and to the expandable member by a plurality of sutures. The sutures can include cross stitches formed around both a wire segment of the first set and a wire segment of the second set at one of the intersection points.

19 Claims, 18 Drawing Sheets





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(58) **Field of Classification Search**
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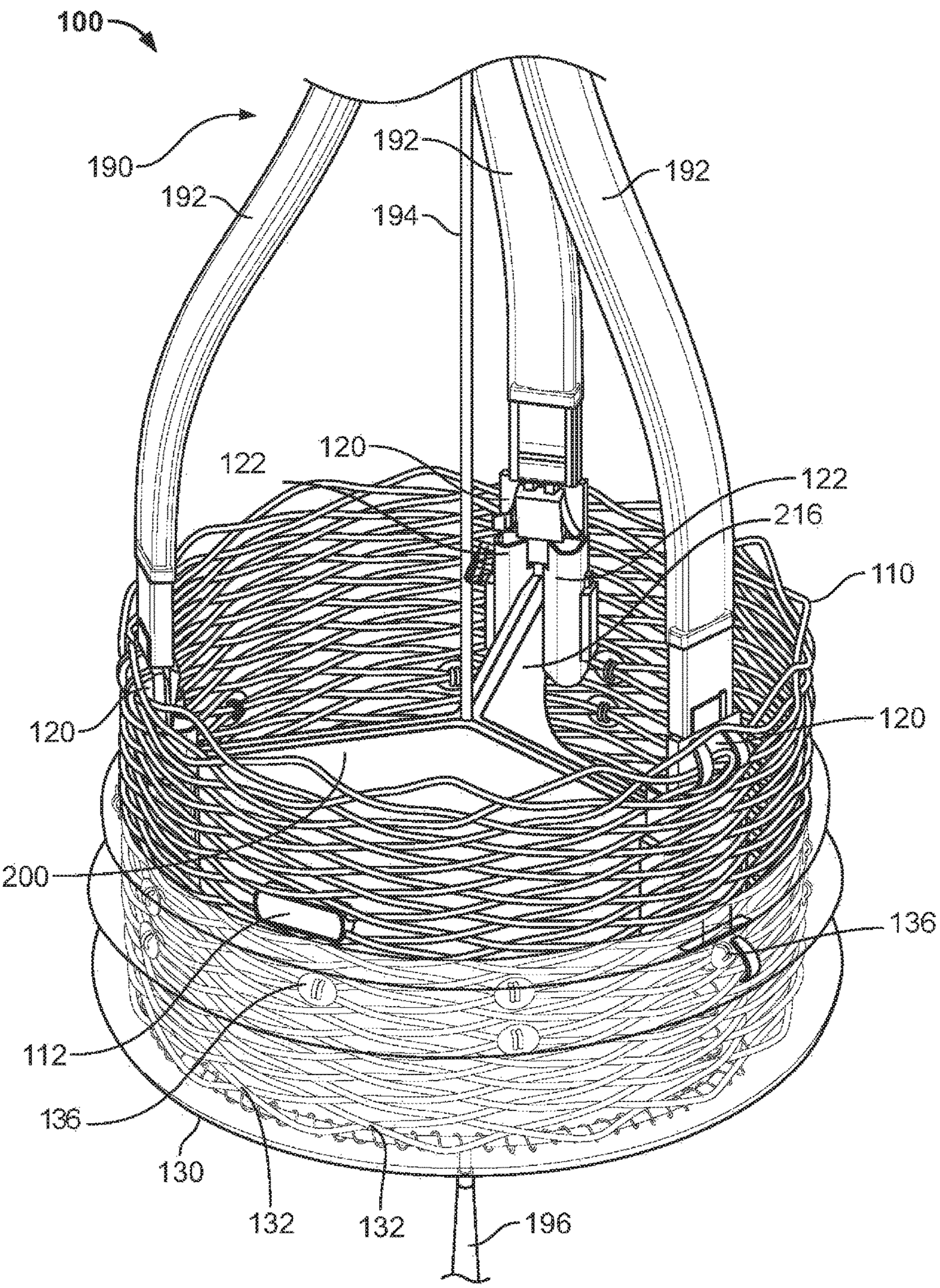
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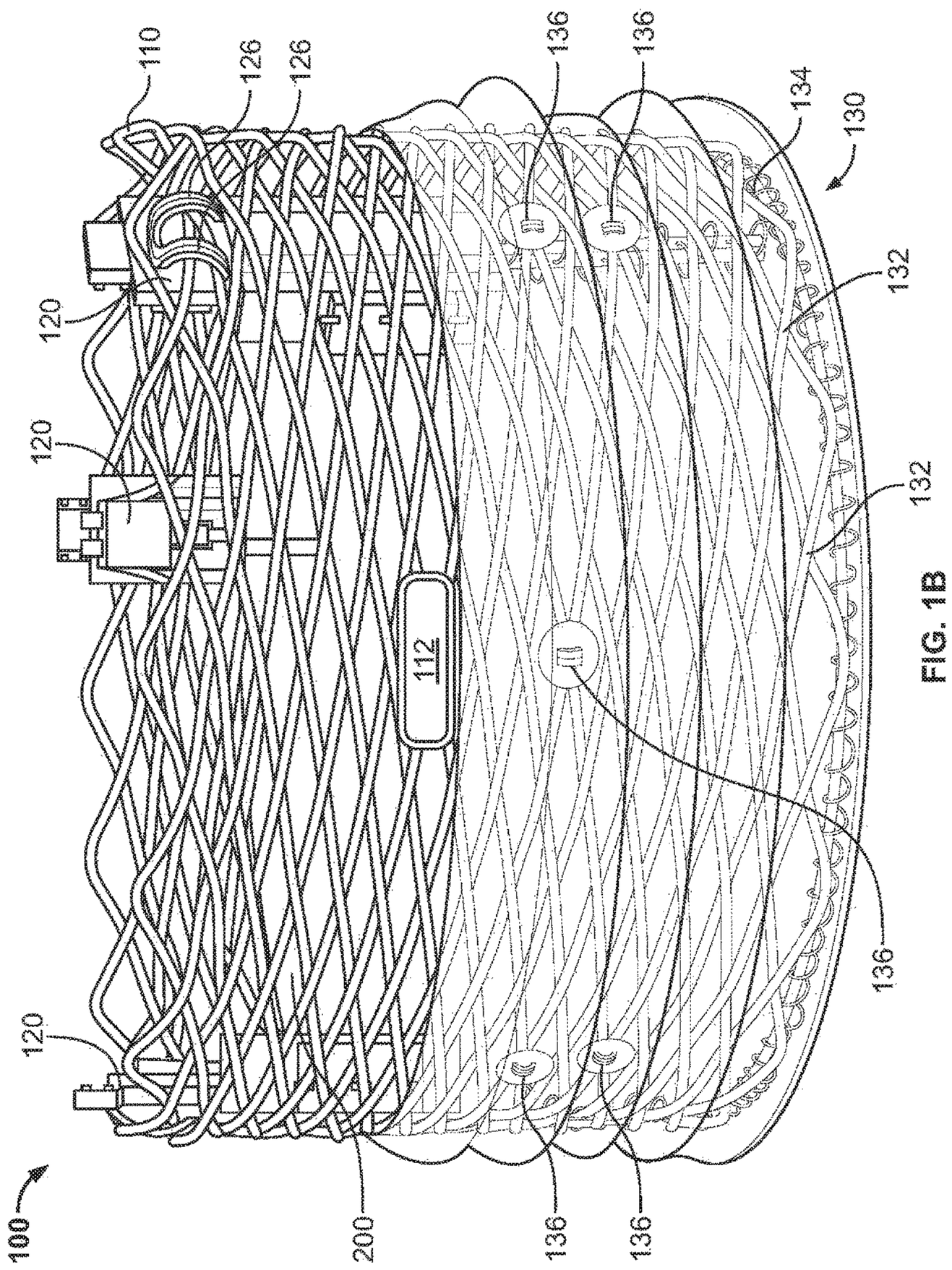
FIG. 1A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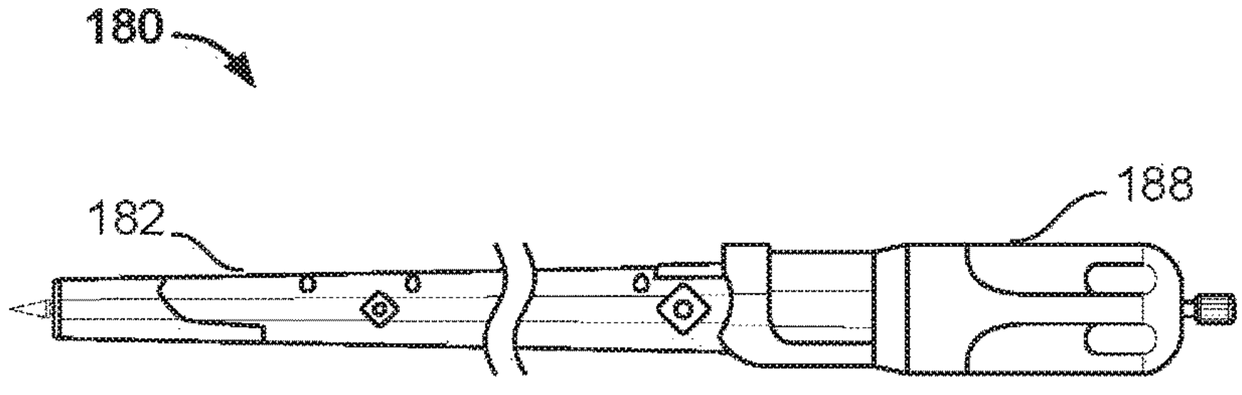

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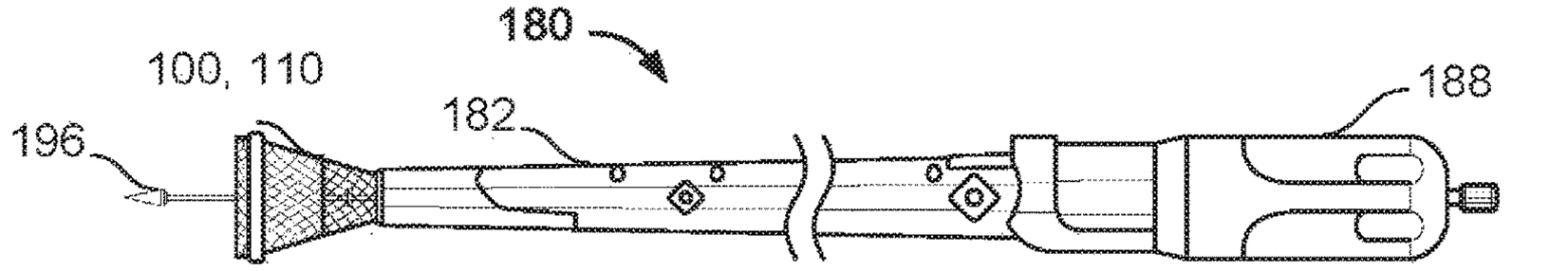

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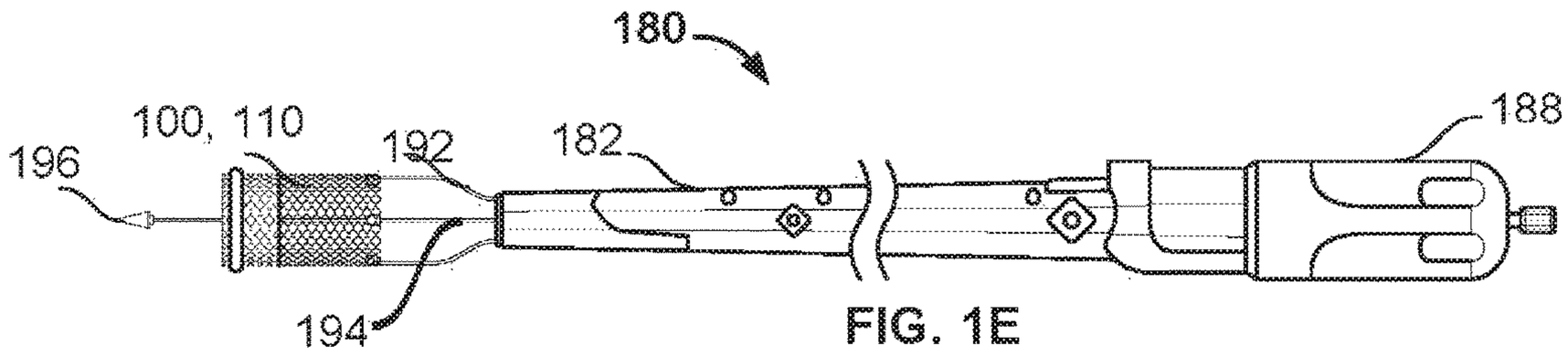

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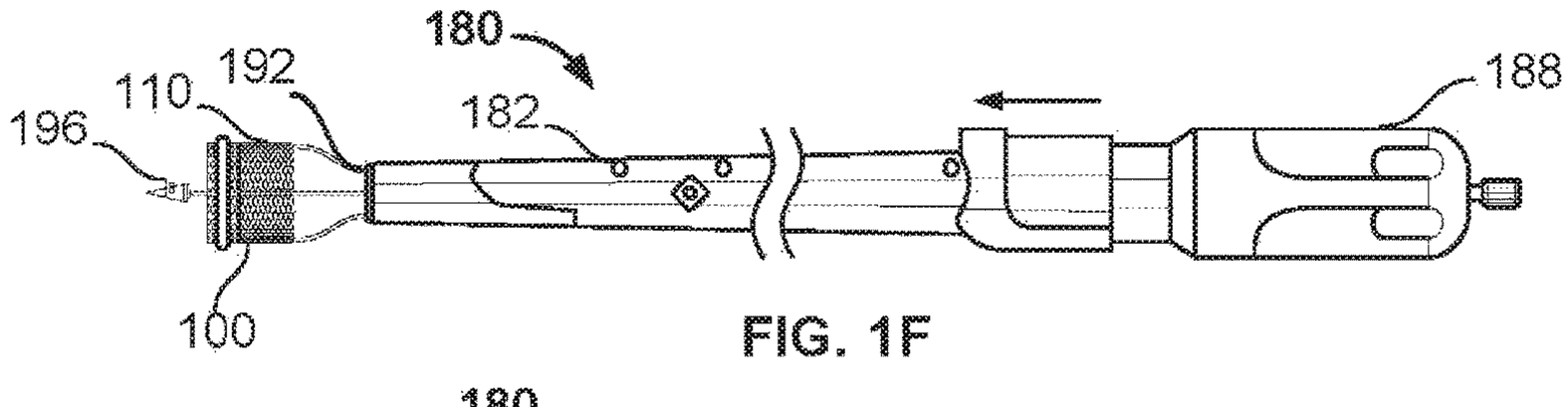

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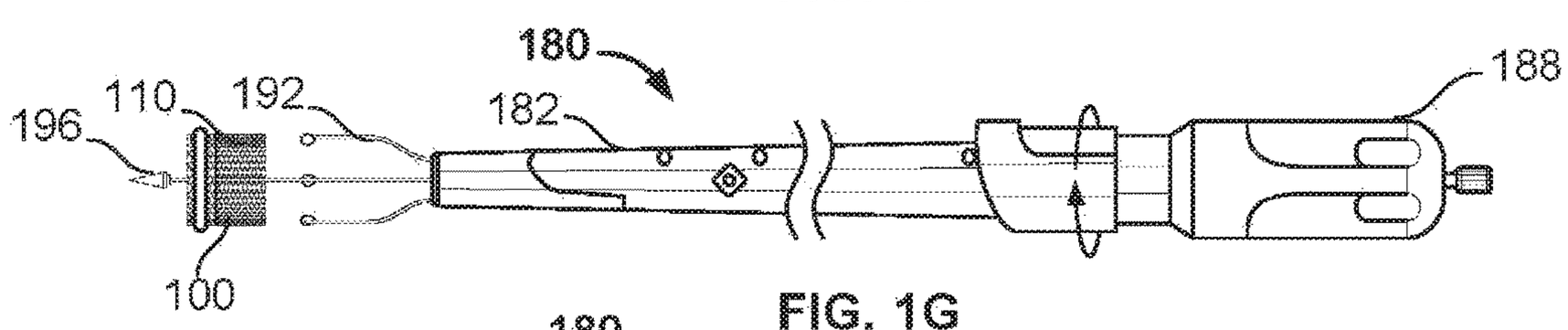

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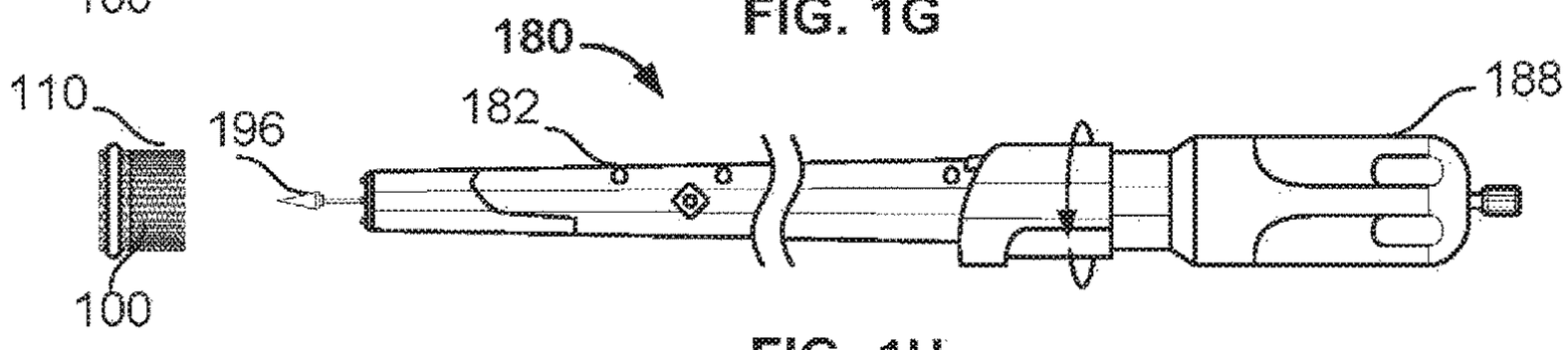

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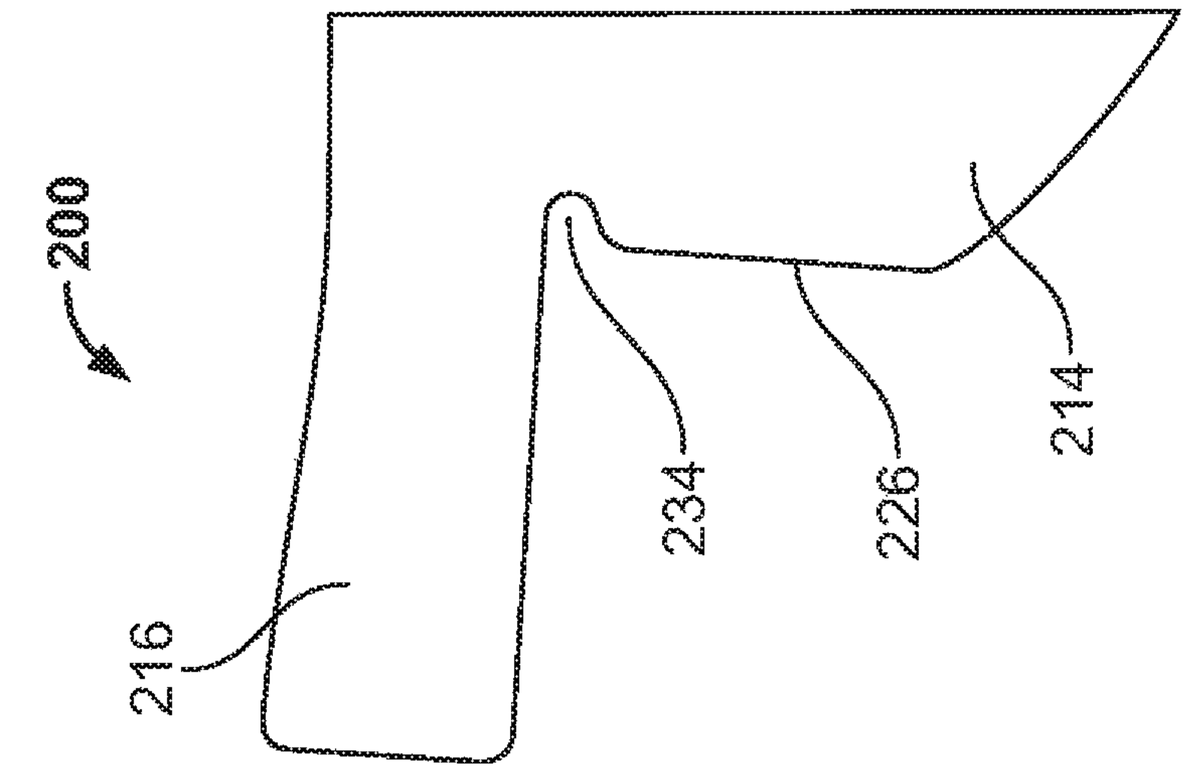

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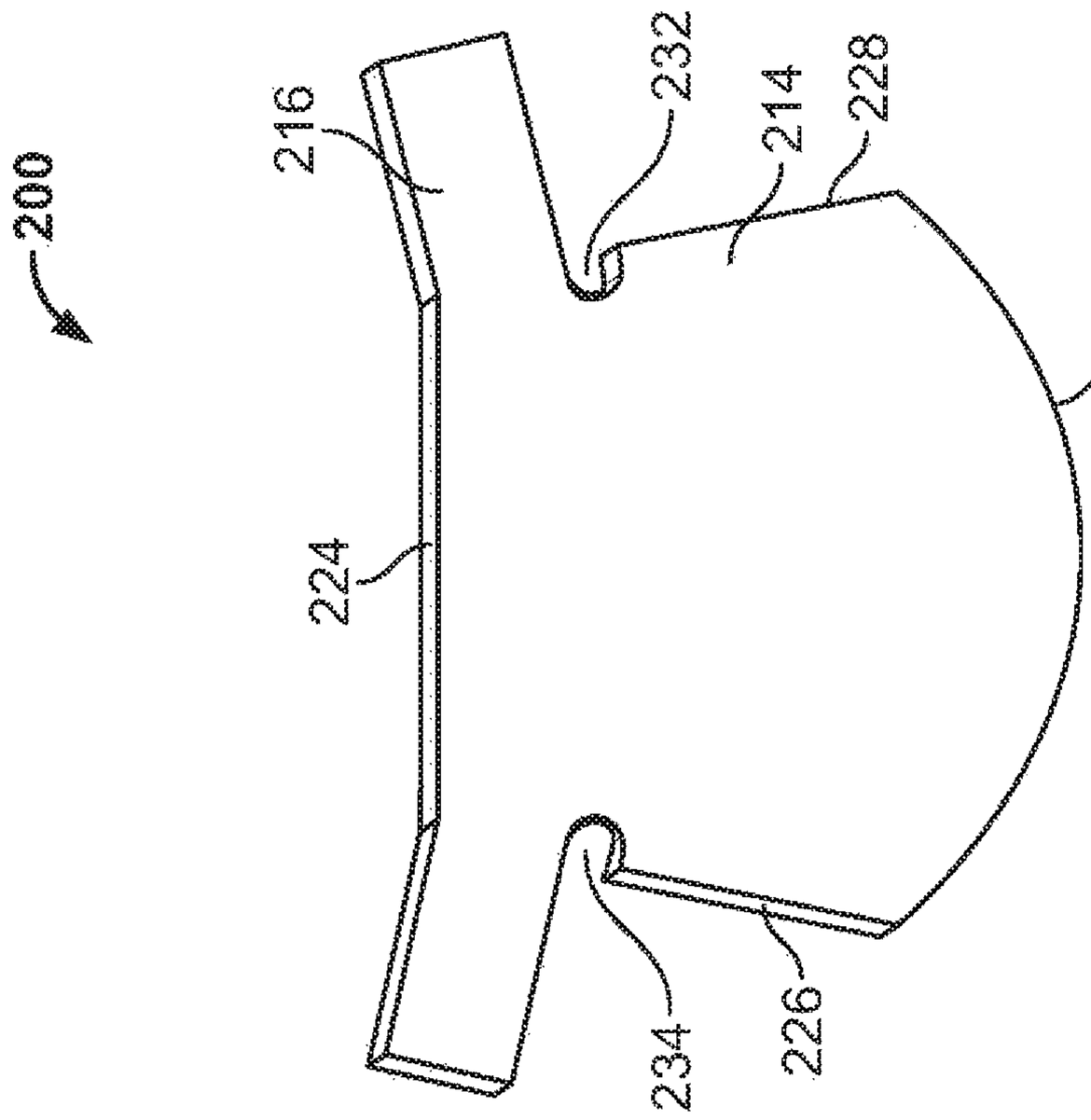

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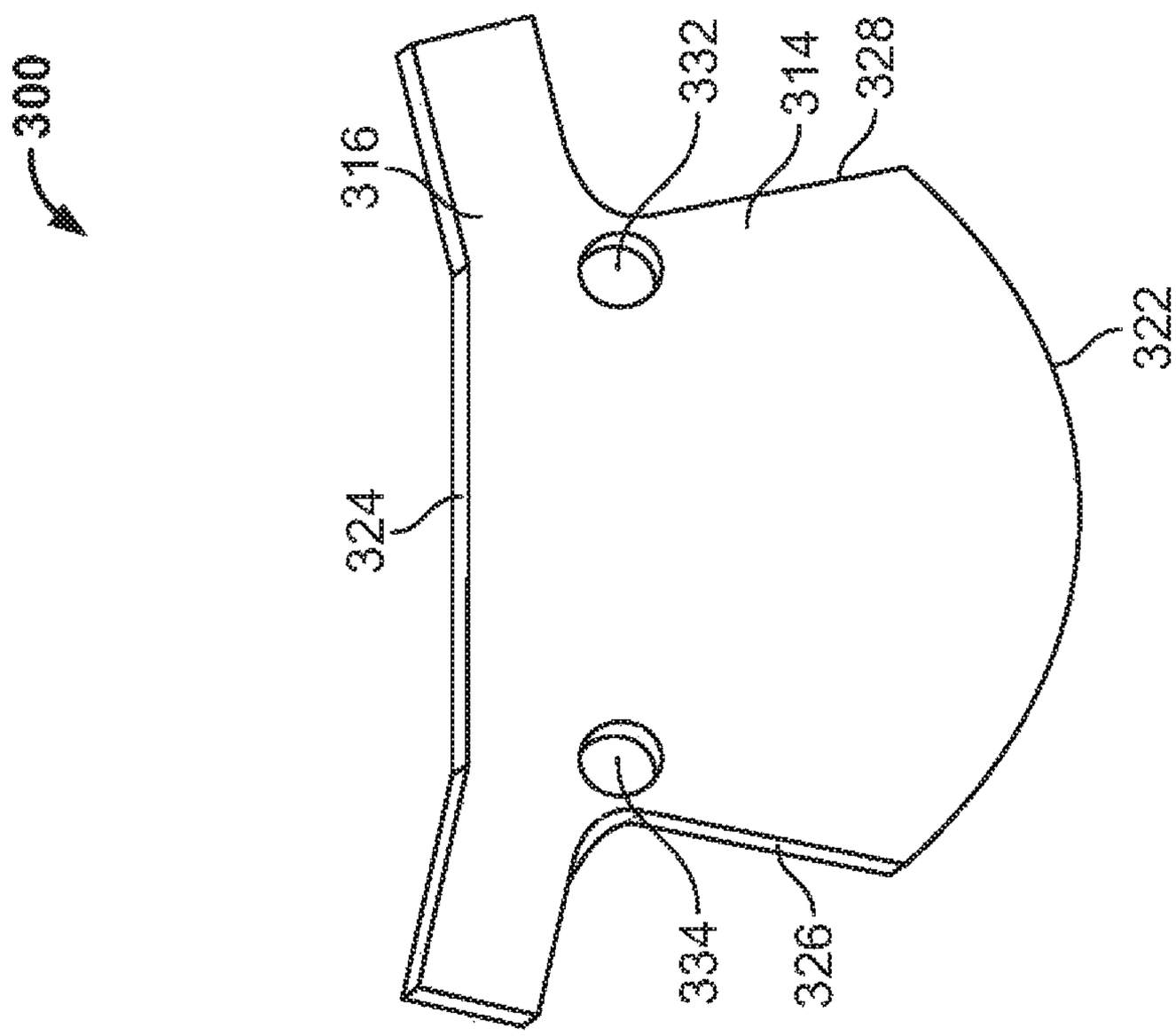
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316
332
314
328
322
324
334
326

FIG. 3

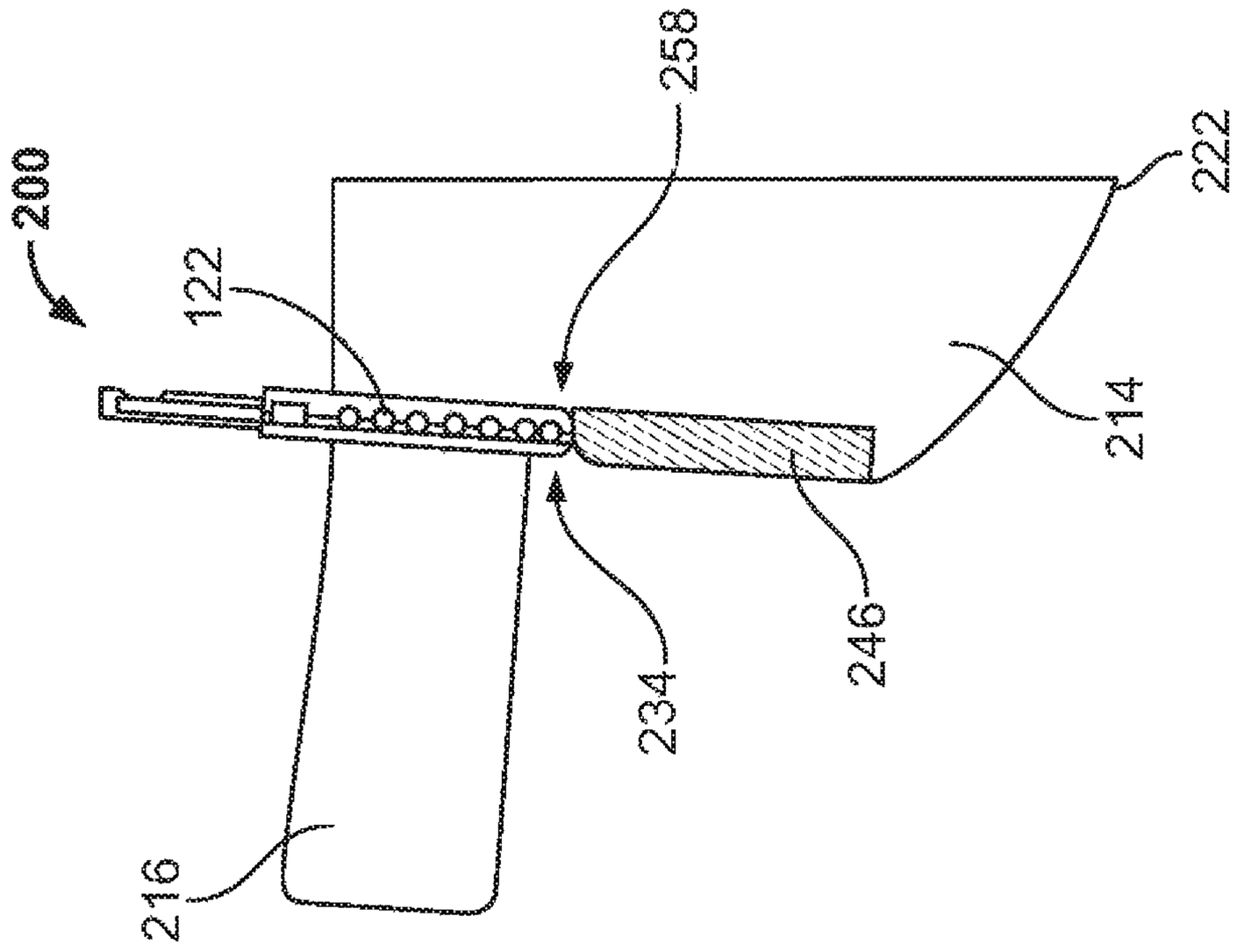
200
258
222
122
214
234
246
216

FIG. 2C

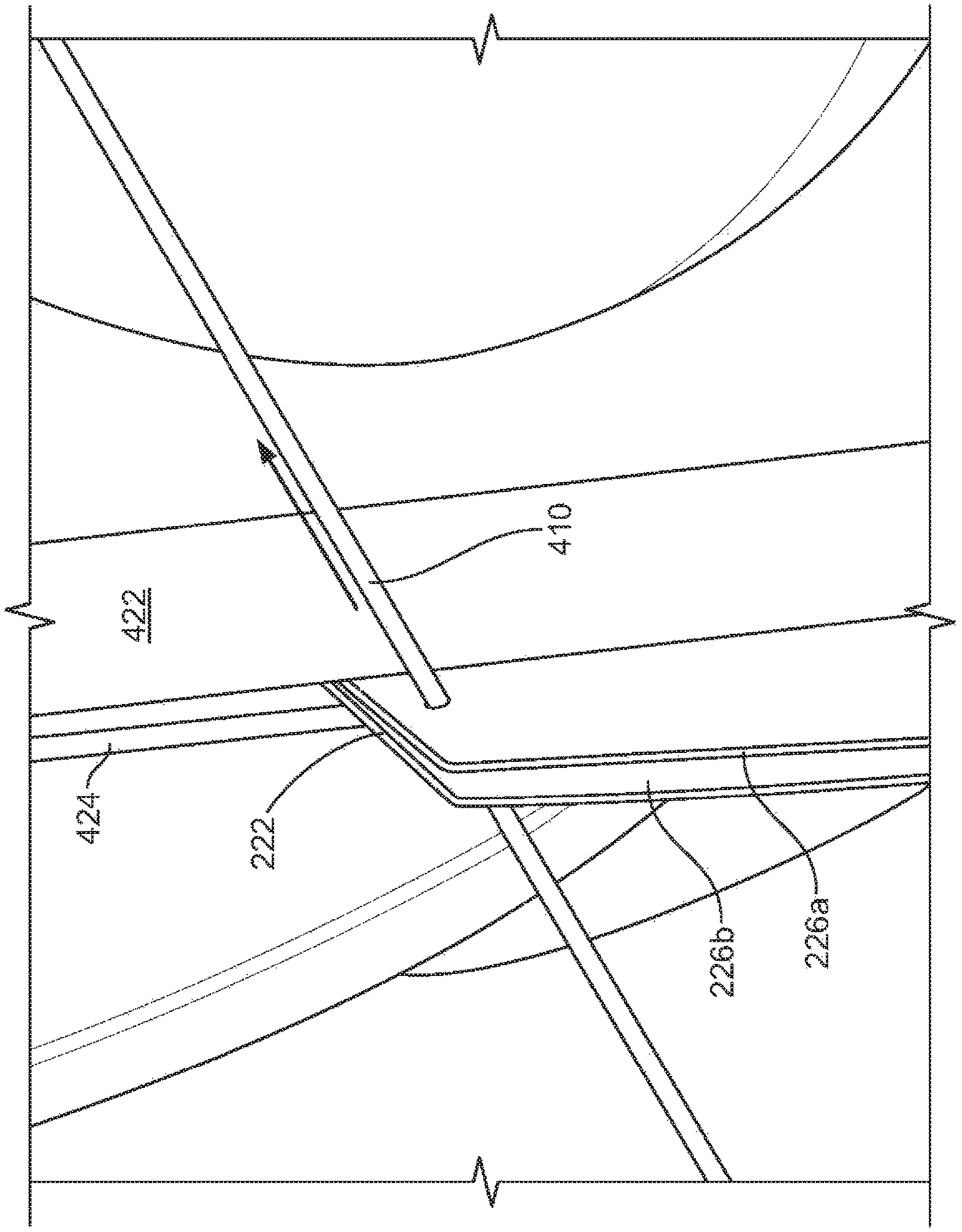

FIG. 4A

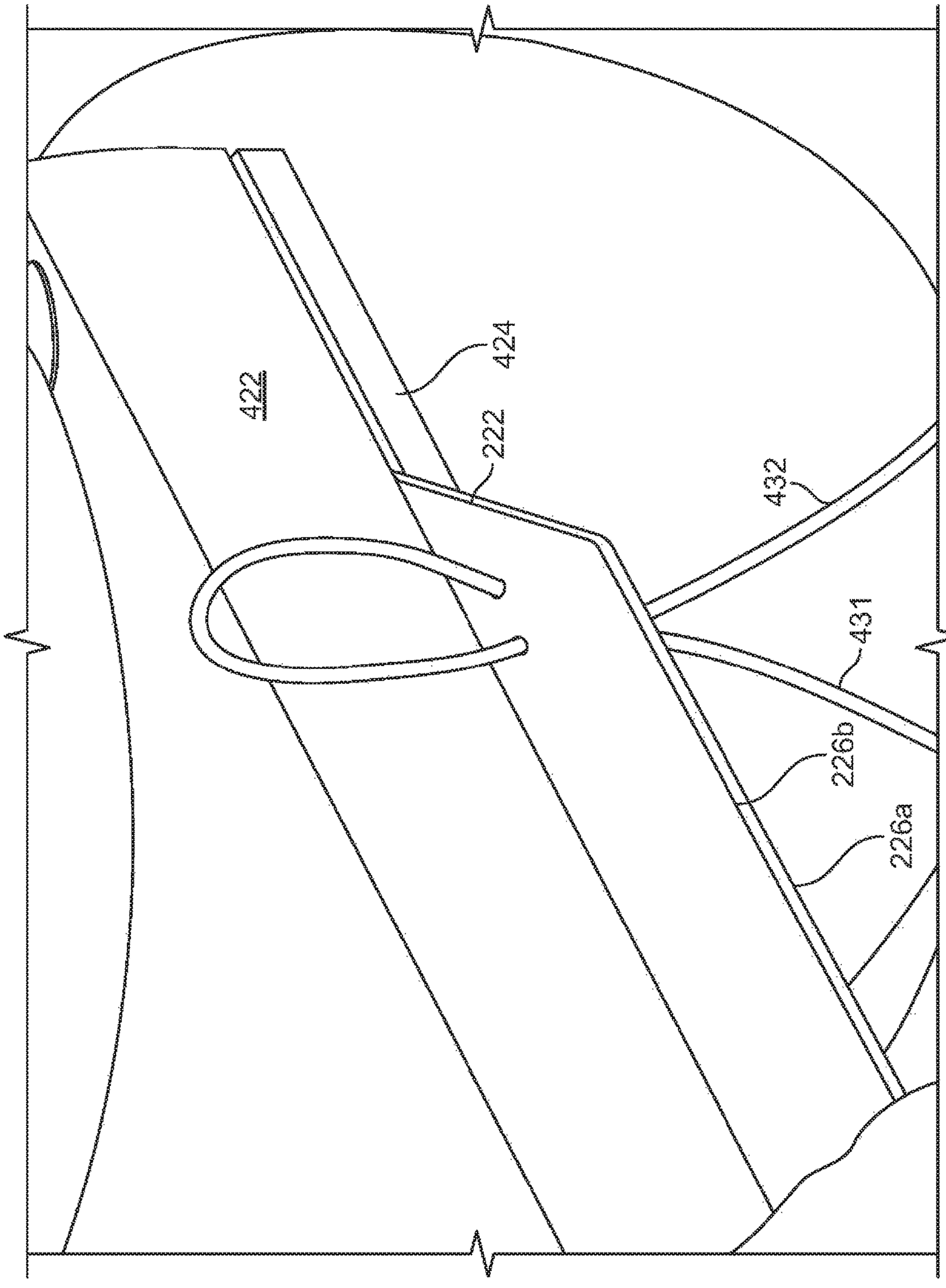

FIG. 4B

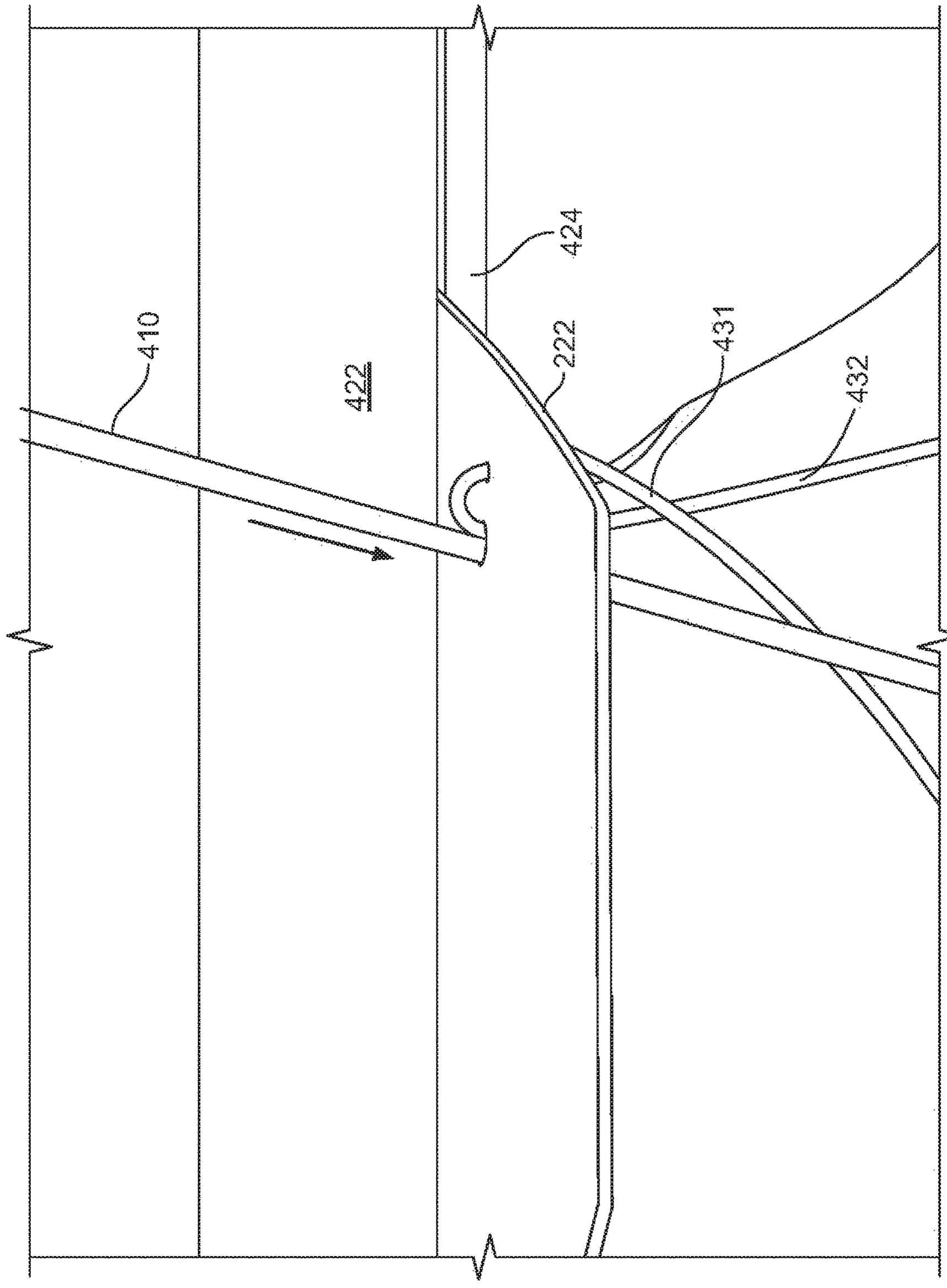

FIG. 4C

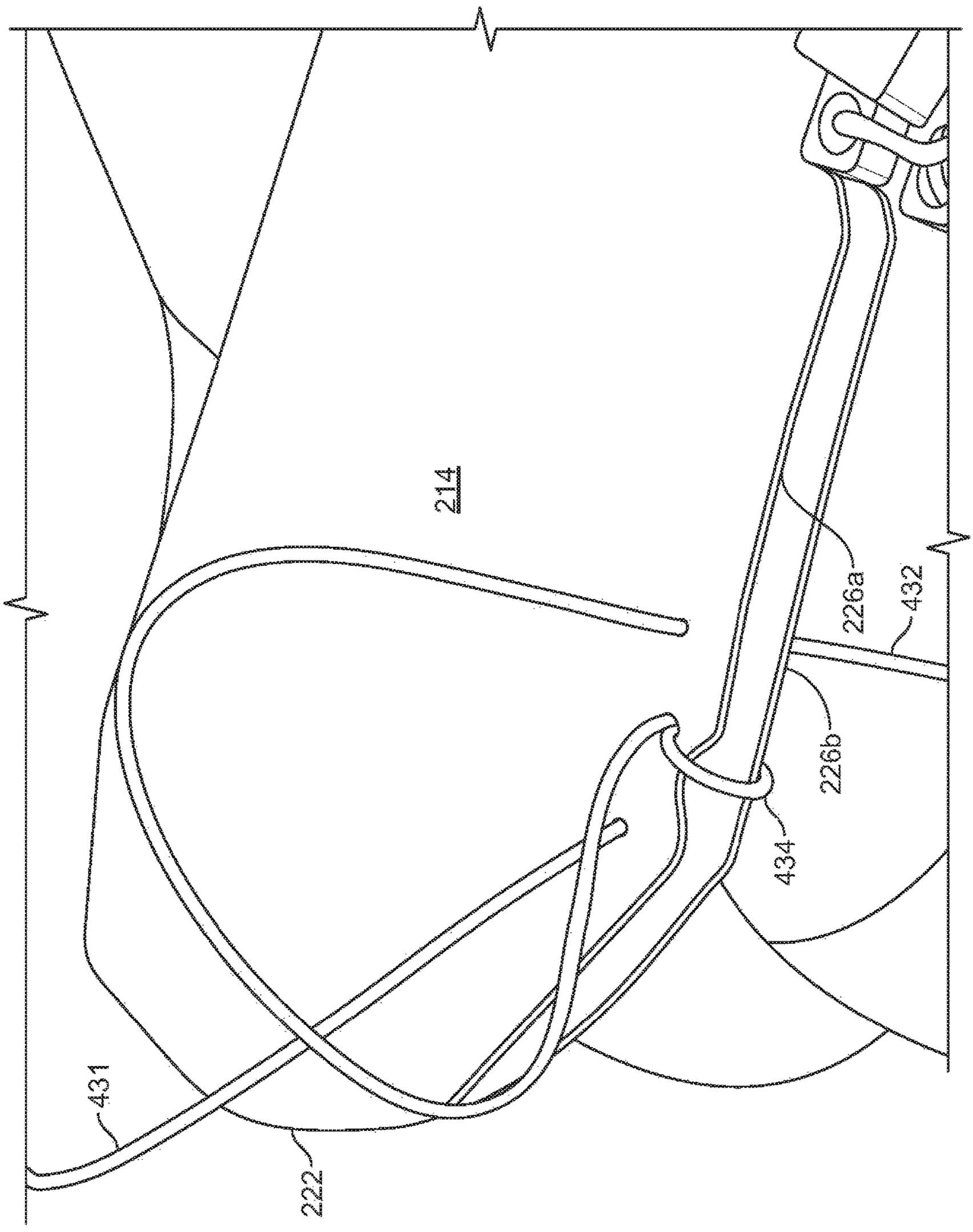

FIG. 4D

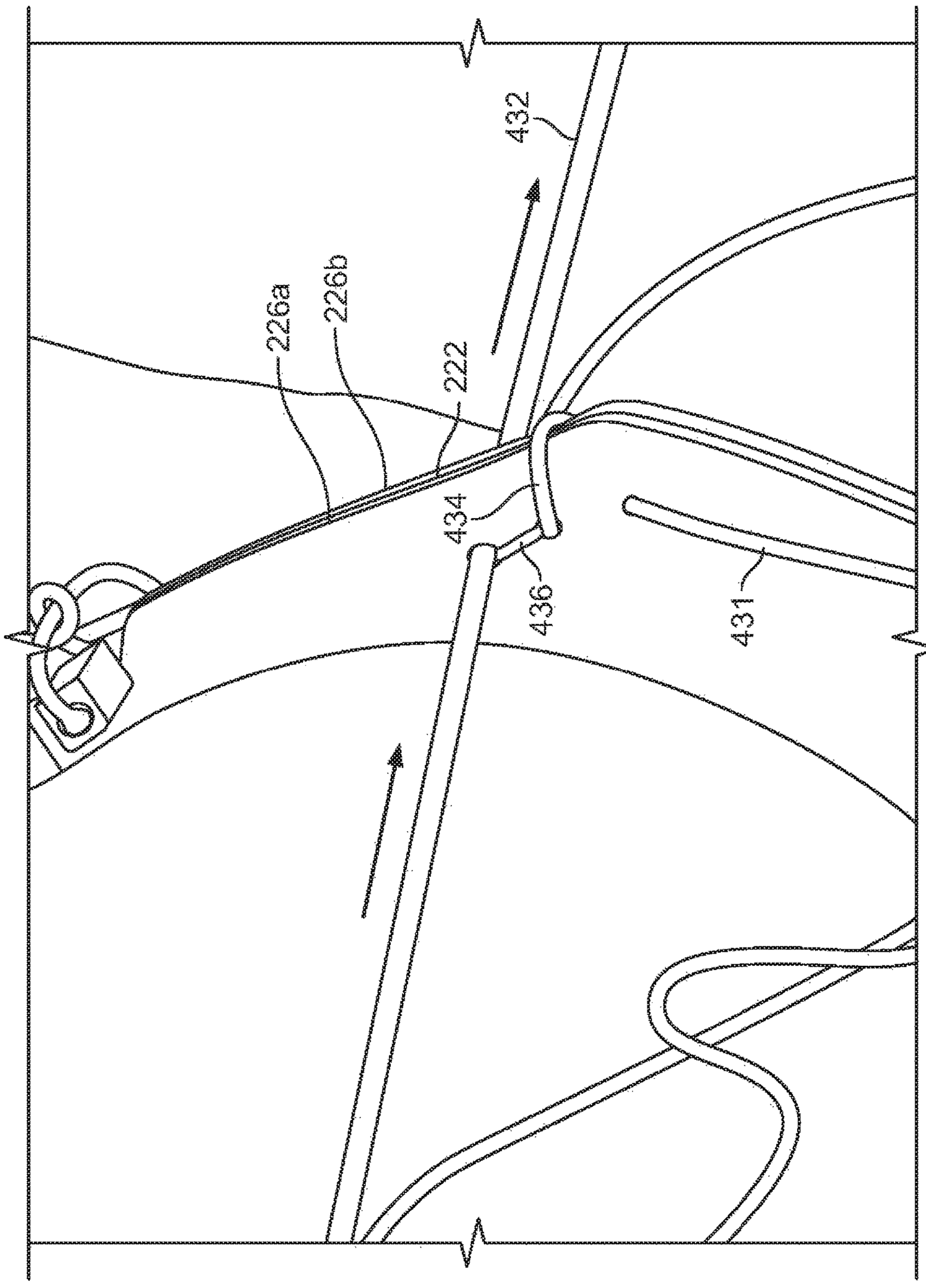

FIG. 4E

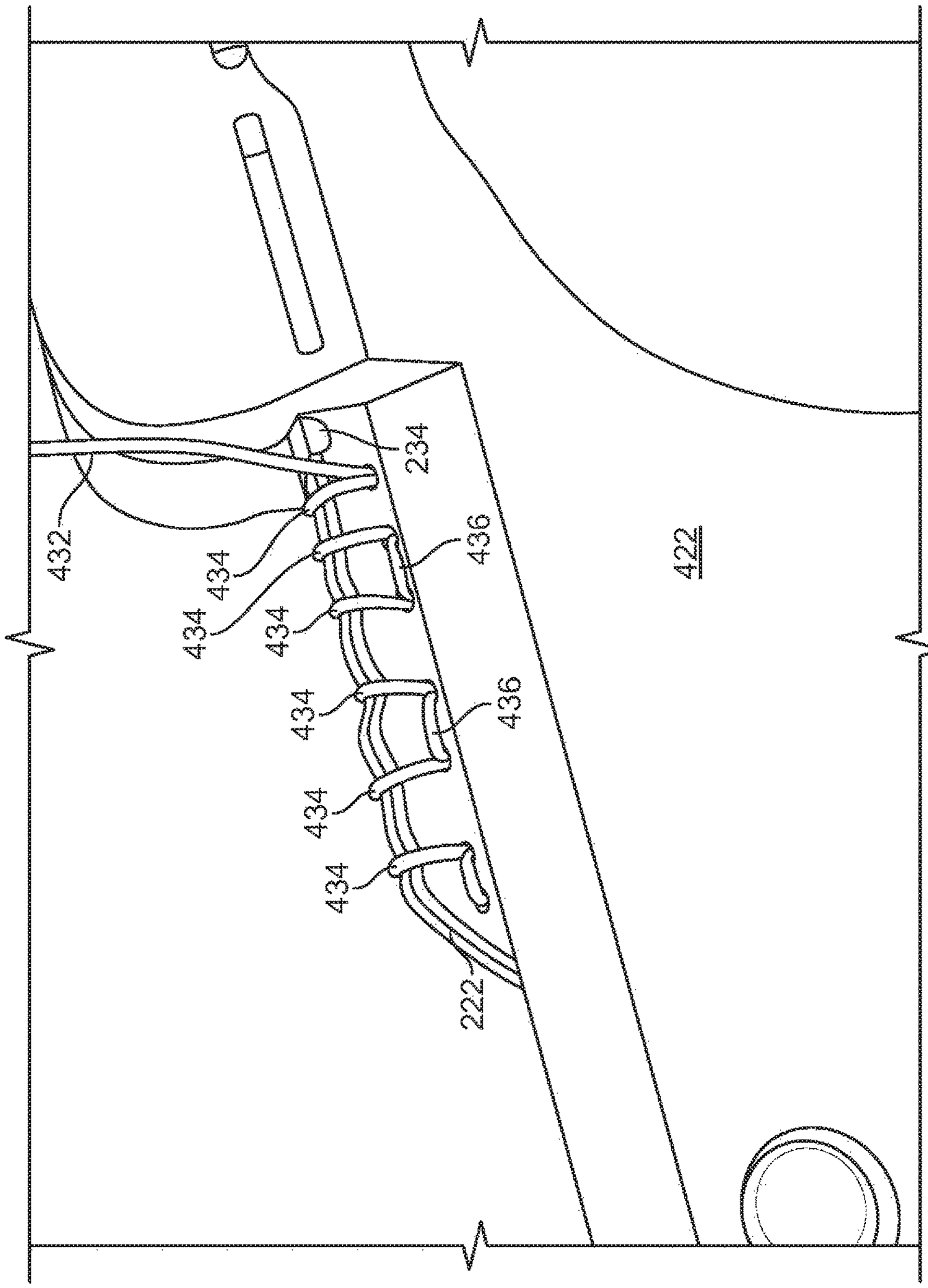

FIG. 4F

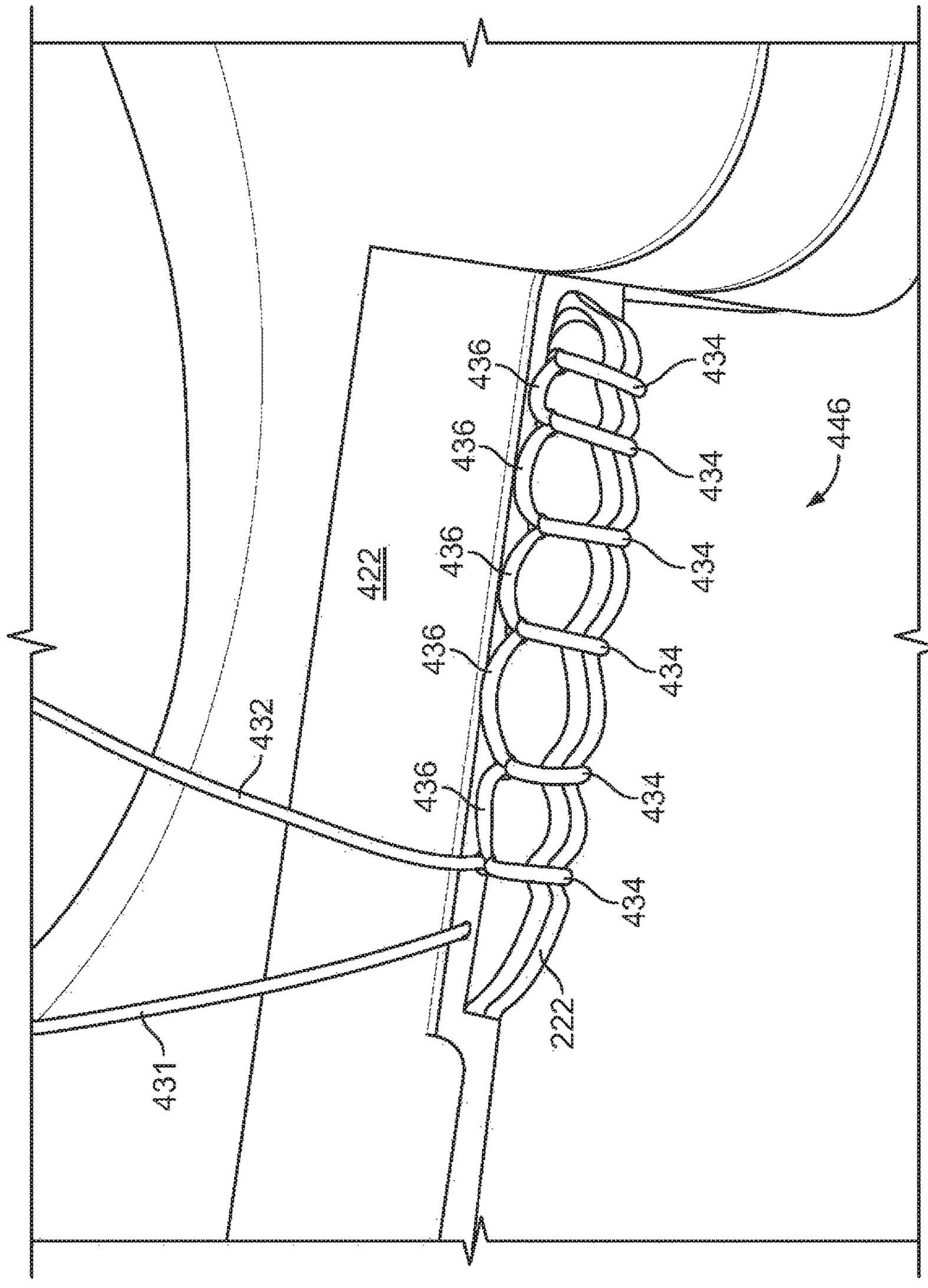

FIG. 4G

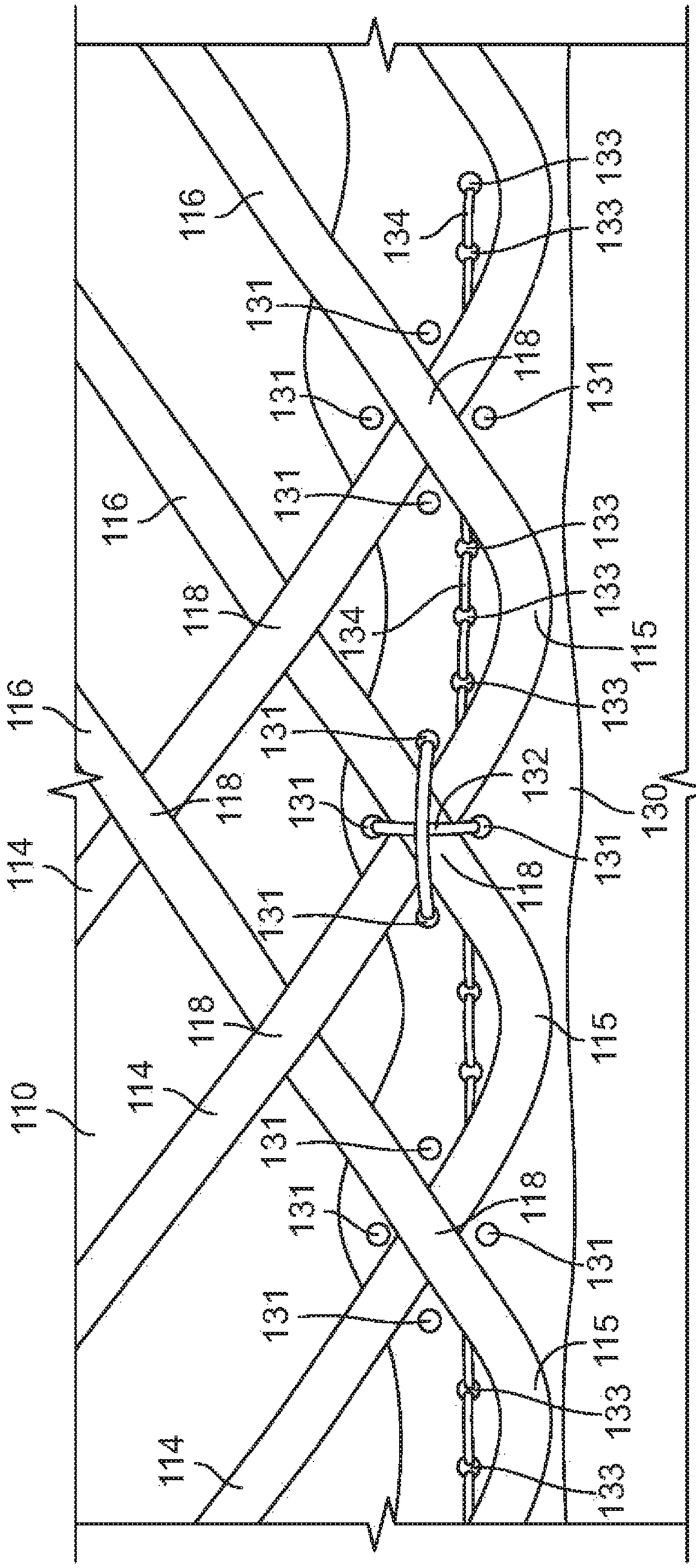

FIG. 5A

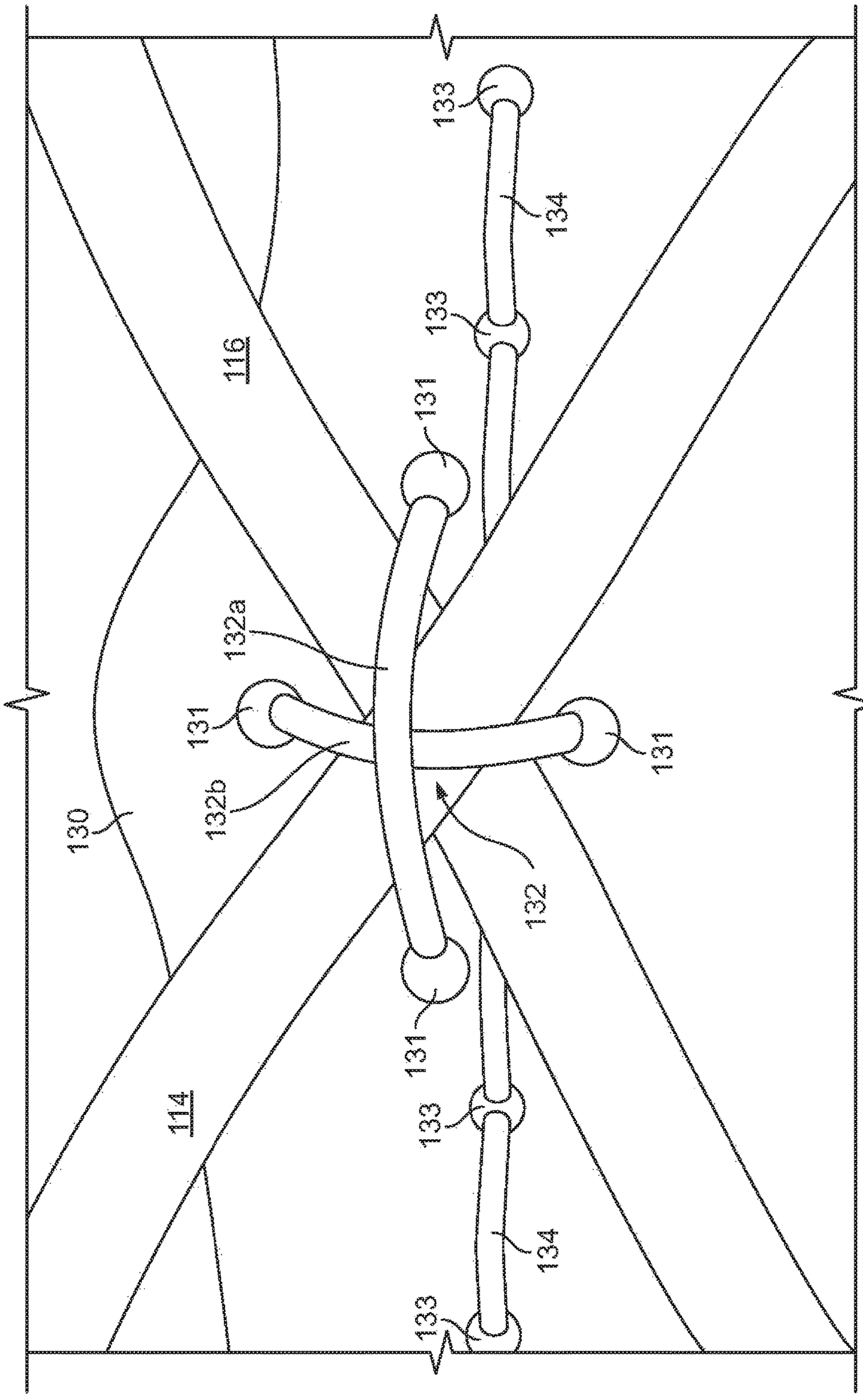
133
134
133
116
131
131
132a
131
132b
131
130
132
131
133
114
134
133

FIG. 5B

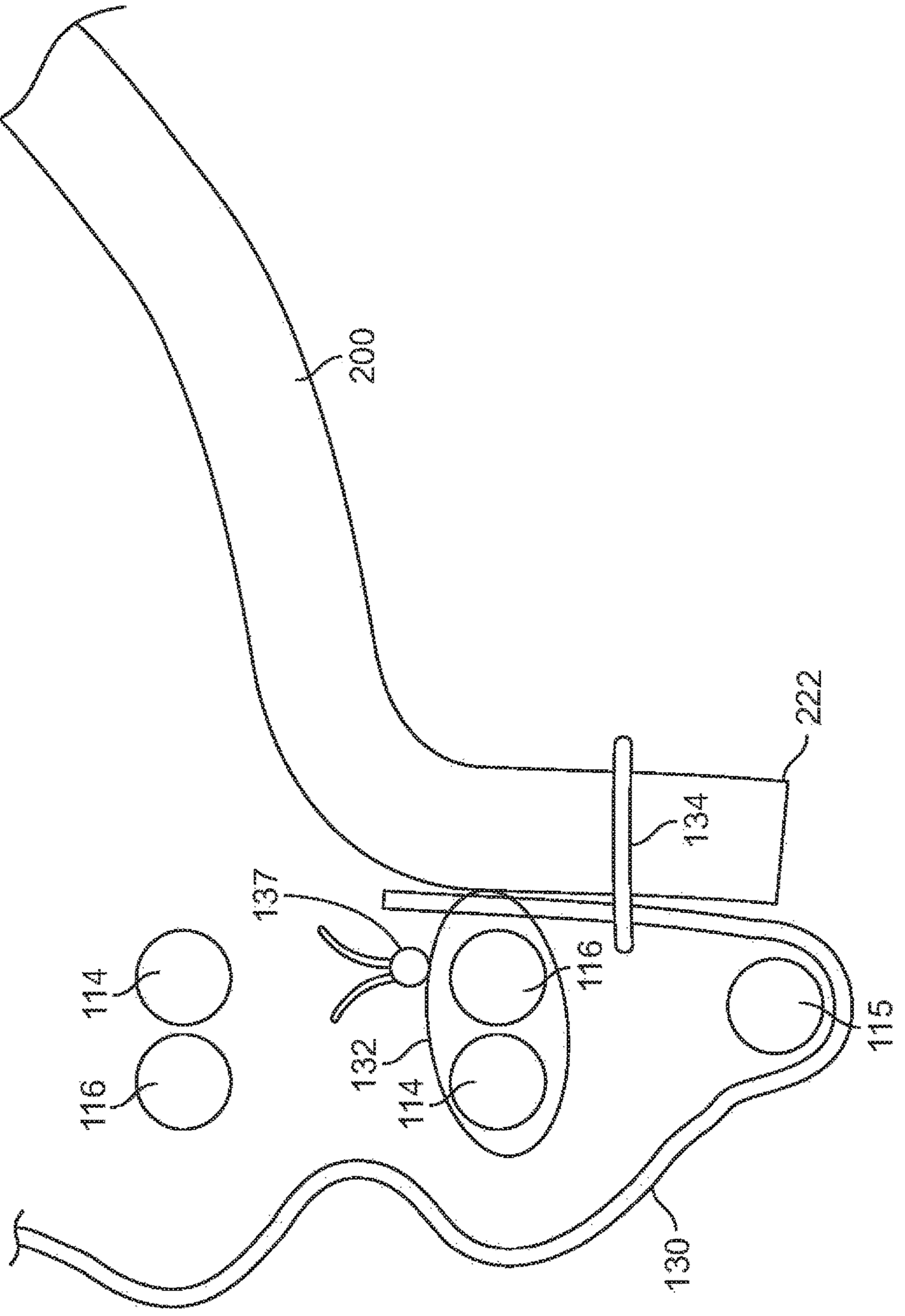

FIG. 5C

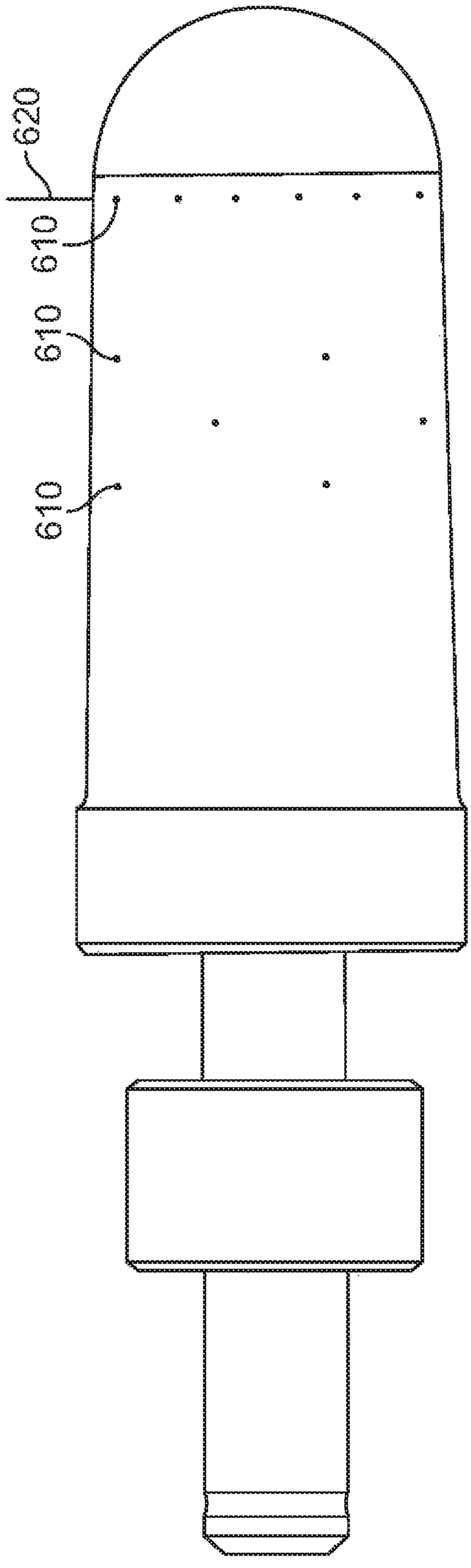

FIG. 6

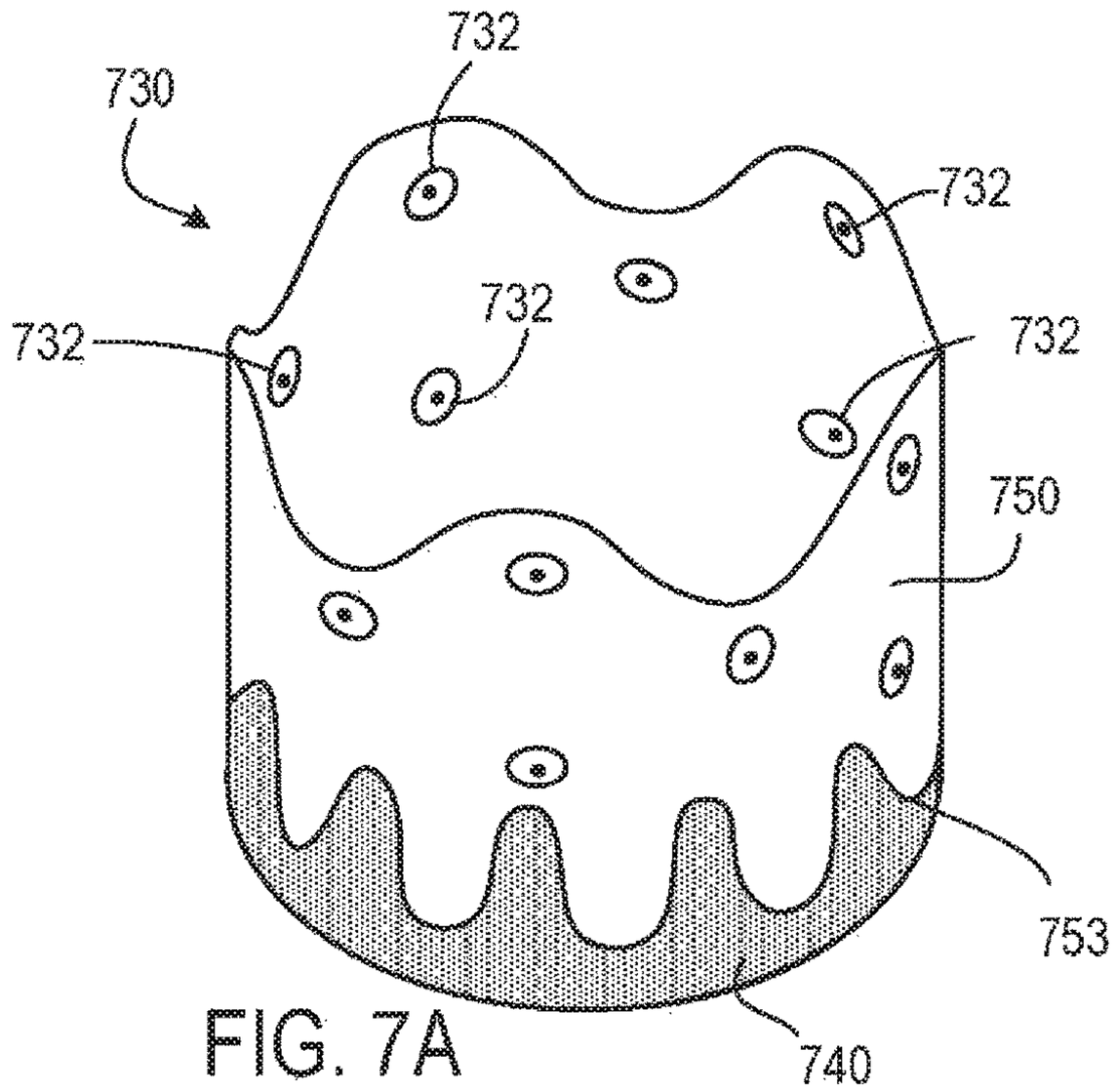

FIG. 7A

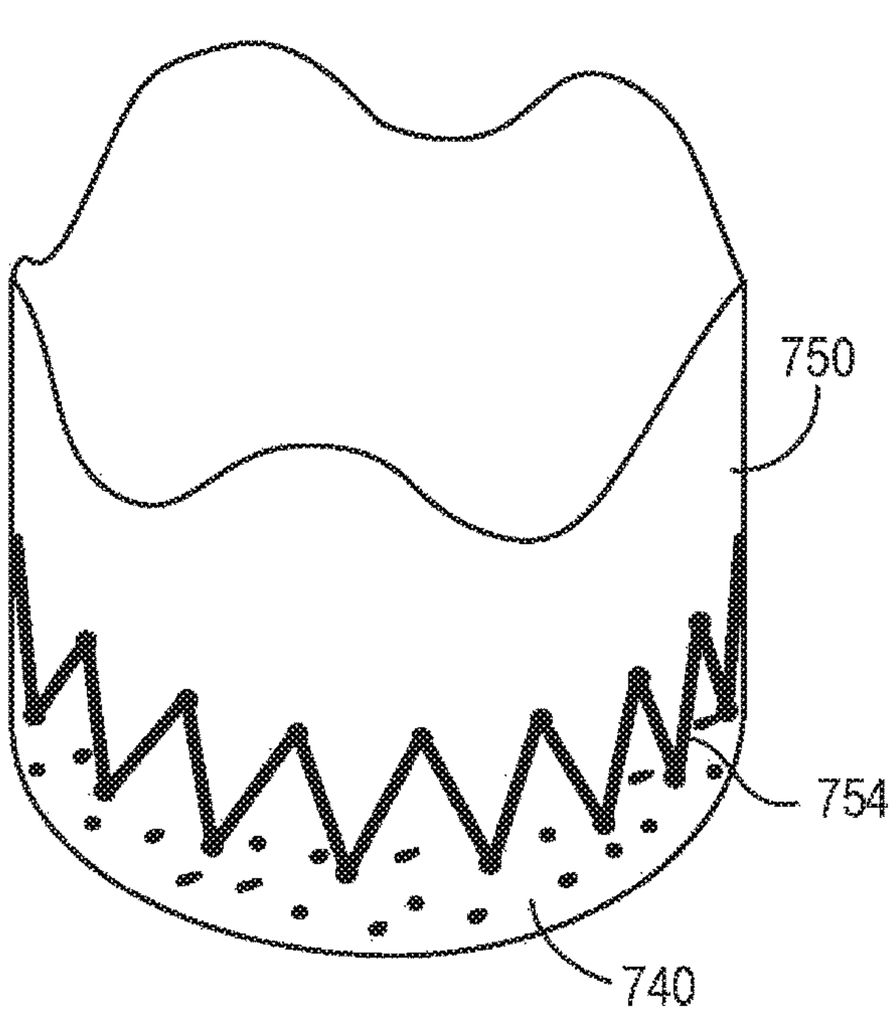

FIG. 7B

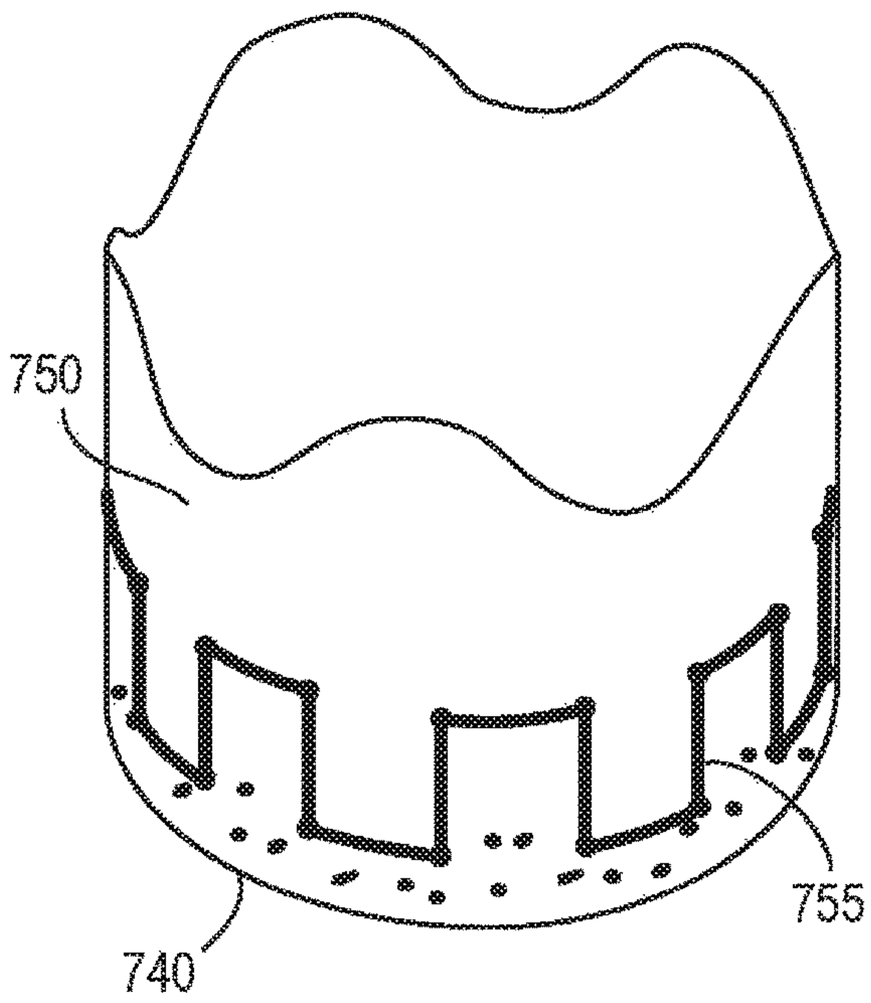

FIG. 7C

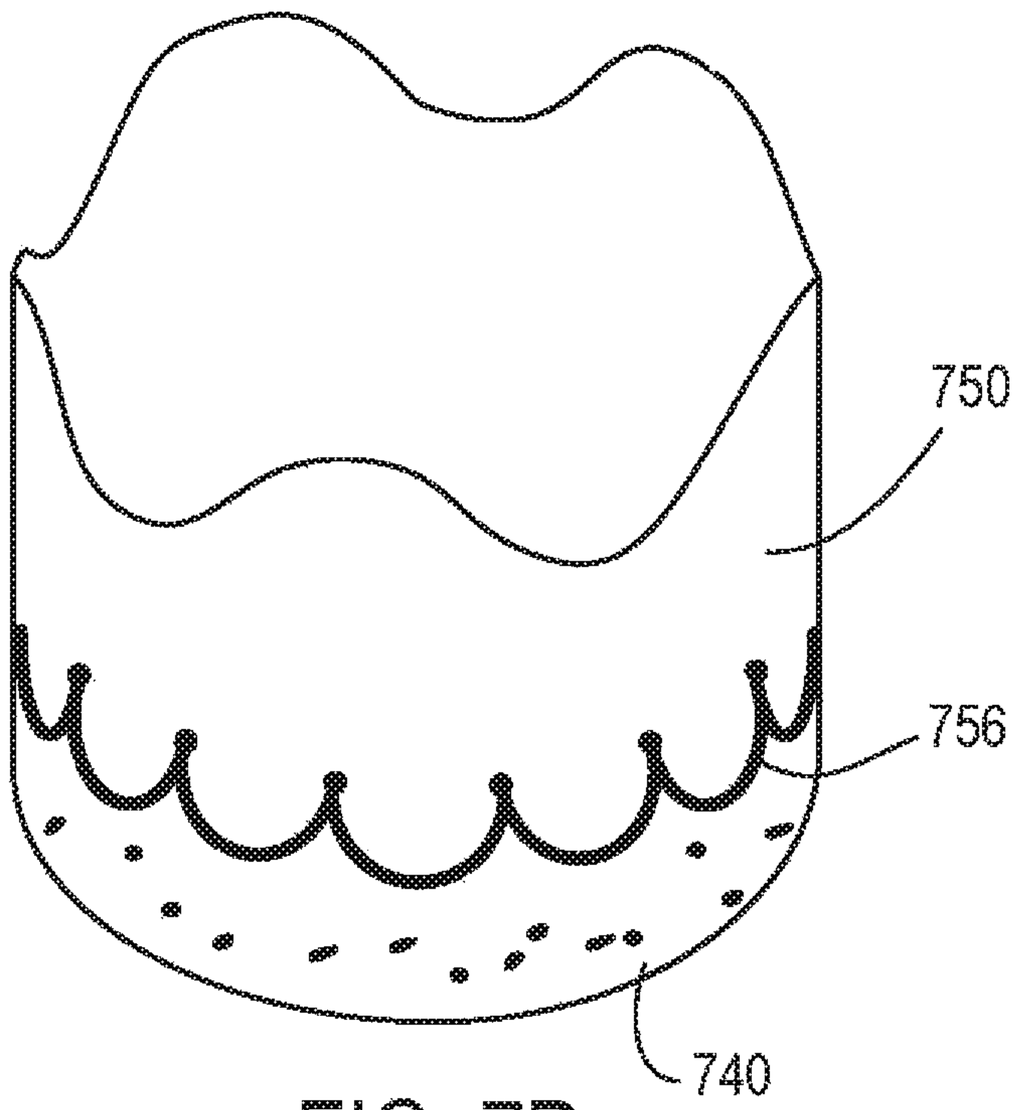

FIG. 7D

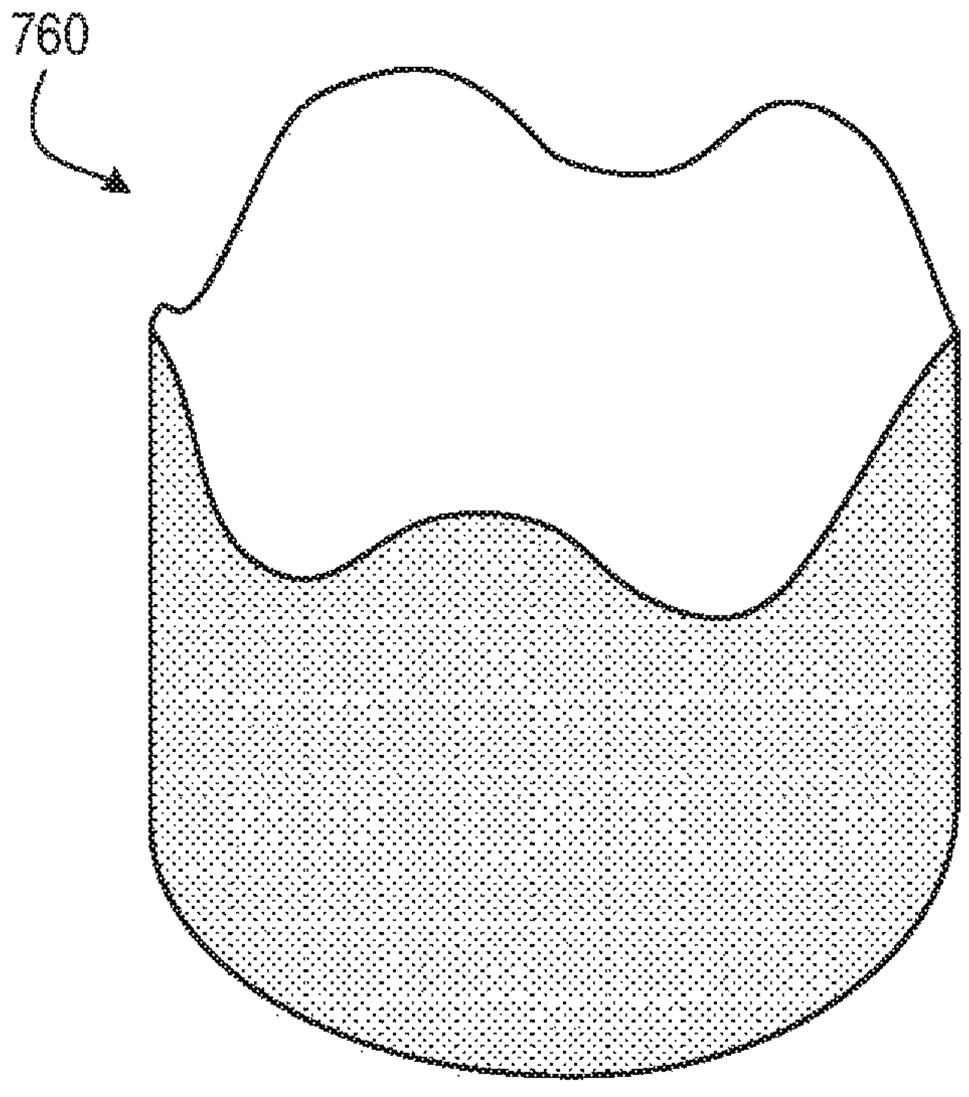

FIG. 7E

PROSTHETIC HEART VALVE HAVING TUBULAR SEAL

RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 62/111,472, file Feb. 3, 2015.

FIELD

This document provides prosthetic heart valves having a tubular seal.

BACKGROUND

The human heart contains four valves: a tricuspid valve, a pulmonic valve, a mitral valve and an aortic valve. The main purpose of the valves is to maintain unimpeded forward flow through the heart and into the major blood vessels connected to the heart, for example, the pulmonary artery and the aorta. As a result of a number of disease processes, both acquired and congenital, any one of the four heart valves may malfunction and result in either stenosis (impeded forward flow) and/or backward flow (regurgitation). Either process burdens the heart and may lead to serious problems, for example, heart failure. Various procedures for fixing or replacing defective heart valves are known in the art. In some cases, artificial heart valves can be implanted in the heart of a patient to replace a diseased or damaged heart valve with a prosthetic equivalent.

Prosthetic heart valves can have a variety of designs. Two major types of prosthetic heart valves include mechanical heart valves and bioprosthetic heart valves. Mechanical heart valves can be made of synthetic materials, such as plastics or metals, while bioprosthetic heart valves can be made of biologic tissue mounted on a fabric covered plastic or metal frame. Bioprosthetic heart valves can include animal tissue, such as porcine or bovine tissue, that has been chemically treated to make the valve suitable for implantation in a human. Bioprosthetic valves do not generally require a patient to undergo anticoagulant therapy, which is typically required when using mechanical valves. As such, there is a need to further improve the design of bioprosthetic valves to retain its functionality during the life of the patient and minimize stenosis and regurgitation.

SUMMARY

Prosthetic heart valves provided herein can have a structure adapted to retain functionality during the life of the patient and minimize stenosis and/or regurgitation by having an improved connection between different parts of a prosthetic heart valve.

In Example 1, a prosthetic heart valve includes an expandable member comprising one or more braided wires, the one or more braided wires comprising a first set of wire segments extended helically in a first direction and a second set of wire segments extended helically in a second direction such that each wire segment of the first set intersects a plurality of wire segments from the second set at a plurality of intersection points, wherein the one or more braided wires have crowns where the wire segments of the first set connect to wire segments of the second set. The prosthetic heart valve can additionally include a plurality of leaflets being secured within the expandable member and a tubular seal comprising an elastomeric material, the tubular seal having an inflow edge being secured to bottom inflow edges of the plurality of leaflets and to the expandable member by a plurality of sutures, characterized by the sutures comprising cross stitches formed around both a wire segment of the first set and a wire segment of the second set at one of the intersection points.

In Example 2, the prosthetic heart valve of Example 1, wherein each cross stitch is an independently tied off stitch unconnected to other cross stitches.

In Example 3, the prosthetic heart valve of either Example 1 or Example 2, wherein each cross stitch is attached at an intersection point immediately adjacent a crown at an inflow side of the expandable member.

In Example 4, the prosthetic heart valve of any of Examples 1-3, wherein the plurality of leaflets are secured together along side edges thereof.

In Example 5, the prosthetic heart valve of Example 4, wherein the plurality of leaflets each comprise two sleeve portions, wherein the sleeve portions are secured to the expandable member by a plurality of anchor elements.

In Example 6, the prosthetic heart valve of any of Examples 1-5, wherein the tubular seal comprises a plurality of non-elastic fibers retained within a matrix of the elastomeric material, the non-elastic fibers being arranged to allow the tubular seal to stretch in an axial or a radial direction.

In Example 7, the prosthetic heart valve of Example 6, wherein the non-elastic fibers are part of a fabric.

In Example 8, the prosthetic heart valve of Example 7, wherein the fabric is a woven fabric.

In Example 9, the prosthetic heart valve of Example 8, wherein the woven fabric comprises fibers in a warp direction and fibers in a waft direction, wherein the fibers in both the warp direction and the waft direction are angled with respect to a central axis of the tubular seal.

In Example 10, the prosthetic heart valve of Example 9, wherein the fibers in both the warp direction and the waft direct are angled at an angle between 5 degrees and 70 degrees with respect to the central axis of the tubular seal.

In Example 11, the prosthetic heart valve of Examples 6-10, wherein the non-elastic fibers are uniformly dispersed throughout the elastomeric polymer matrix.

In Example 12, the prosthetic heart valve of Example 11, wherein the tubular seal has a substantially uniform thickness.

In Example 13, the prosthetic heart valve of any of Examples 1-10, wherein the tubular seal comprises an outflow end region and an inflow end region, the inflow end region being a portion of the tubular seal comprising a fabric within a matrix of the elastomeric matrix, wherein the fabric has a non-linear edge defining an interface between the inflow end region and the outflow end region.

In Example 14, the prosthetic heart valve of Example 13, wherein the non-linear edge of the fabric has a sinusoidal or scalloped shape.

In Example 15, the prosthetic heart valve of any of Example 1-14, wherein the plurality of leaflets are secured to the tubular seal by a continuous circumferential running stitch.

In Example 16, a prosthetic heart valve can include an expandable member comprising one or more braided wires, the one or more braided wires comprising a first set of wire segments extended helically in a first direction and a second set of wire segments extended helically in a second direction such that each wire segment of the first set intersects a plurality of wire segments from the second set at a plurality of intersection points, wherein the one or more braided wires have crowns where the wire segments of the first set connect to wire segments of the second set. The prosthetic heart

valve can additionally include a plurality of leaflets being secured within the expandable member and a tubular seal comprising an elastomeric material, the tubular seal having an inflow edge being secured to bottom inflow edges of the plurality of leaflets and to the expandable member by a plurality of sutures, characterized by the sutures comprising cross stitches formed around both a wire segment of the first set and a wire segment of the second set at one of the intersection points.

In Example 17, the prosthetic heart valve of Example 16, wherein each cross stitch is an independently tied off stitch unconnected to other cross stitches.

In Example 18, the prosthetic heart valve of Example 16, wherein each cross stitch is attached at an intersection point immediately adjacent a crown at an inflow side of the expandable member.

In Example 19, the prosthetic heart valve of Example 16, wherein the plurality of leaflets are secured together along side edges thereof.

In Example 20, the prosthetic heart valve of Example 19, wherein the plurality of leaflets each comprise two sleeve portions, wherein the sleeve portions are secured to the expandable member by a plurality of anchor elements.

In Example 21, the prosthetic heart valve of Example 16, wherein the tubular seal comprises a plurality of non-elastic fibers retained within a matrix of the elastomeric material, the non-elastic fibers being arranged to allow the tubular seal to stretch in an axial or a radial direction.

In Example 22, the prosthetic heart valve of Example 21, wherein the non-elastic fibers are part of a fabric.

In Example 23, the prosthetic heart valve of Example 22, wherein the fabric has a thickness ranging from about 40 to about 80 microns.

In Example 24, the prosthetic heart valve of Example 22, wherein the fabric is a woven fabric.

In Example 25, the prosthetic heart valve of Example 24, wherein the woven fabric comprises fibers in a warp direction and fibers in a waft direction, wherein the fibers in both the warp direction and the waft direction are angled with respect to a central axis of the tubular seal.

In Example 26, the prosthetic heart valve of Example 25, wherein the fibers in both the warp direction and the waft direct are angled at an angle between 5 degrees and 70 degrees with respect to the central axis of the tubular seal.

In Example 27, the prosthetic heart valve of Example 22, wherein the fibers are made of polyester.

In Example 28, the prosthetic heart valve of Example 21, wherein the non-elastic fibers are uniformly dispersed throughout the matrix.

In Example 29, the prosthetic heart valve of Example 16, wherein the tubular seal has a substantially uniform thickness.

In Example 30, a prosthetic heart valve includes an expandable member comprising one or more braided wires, the one or more braided wires comprising a first set of wire segments and a second set of wire segments such that each wire segment of the first set intersects a plurality of wire segments from the second set at a plurality of intersection points. The prosthetic heart valve can also include a plurality of leaflets secured within the expandable member and a tubular seal including an elastomeric material. The tubular seal can have an inflow edge being secured to bottom inflow edges of the plurality of leaflets and to the expandable member by a plurality of sutures. The sutures can include cross stitches formed around both a wire segment of the first set and a wire segment of the second set at one of the intersection points, wherein the tubular seal comprises an outflow end region and an inflow end region. The inflow end region can be a portion of the tubular seal including a fabric within a matrix of an elastomeric matrix, wherein the fabric has a non-linear edge defining an interface between the inflow end region and the outflow end region.

In Example 31, the prosthetic heart valve of Example 30, wherein the non-linear edge of the fabric has a sinusoidal or scalloped shape.

In Example 32, the prosthetic heart valve of Example 30, wherein the plurality of leaflets are secured to the tubular seal by a continuous circumferential running stitch.

In Example 33, the prosthetic heart valve of Example 30, wherein the first set of wire segments extends helically in a first direction and a second set of wire segments extends helically in a second direction.

In Example 34, the prosthetic heart valve of Example 33, wherein the one or more braided wires have crowns where the wire segments of the first set connect to wire segments of the second set.

In Example 35, a method of making a tubular seal of a prosthetic heart valve includes forming a tubular seal that includes a fabric within a matrix by dipping a mandrel with a first coating composition that has at least one elastomeric polymer. The method can also include drying the first coating composition. The method can also include positioning the fabric on the mandrel and applying a second coating composition on the mandrel. The second coating composition can be different than the first coating composition. The method can further include removing the tubular seal from the mandrel.

The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF DRAWINGS

FIGS. **1**A-**1**H illustrate an exemplary prosthetic heart valve and an exemplary deployment device provided herein. FIG. **1**A is a perspective view of the heart valve connected to the deployment device. FIG. **1**B is a side view of the exemplary prosthetic heart valve. FIGS. **1**C-**1**H illustrate how the exemplary heart valve provided herein can be delivered by the deployment device.

FIGS. **2**A-**2**C illustrates an exemplary leaflet, which can be used in prosthetic heart valves provided herein. FIG. **2**A illustrates a rounded notch in a leaflet where a leaflet can be secured to an adjacent leaflet. FIGS. **2**B and **2**C illustrate a portion of an exemplary leaflet for prosthetic heart valves. FIG. **2**B depicts the rounded notch in an armpit of a leaflet. FIG. **2**C depicts attachment elements in the armpit of the leaflet.

FIG. **3** illustrates another exemplary leaflet, which can be used in prosthetic heart valves provided herein. FIG. **3** depicts apertures in a body of the exemplary leaflet.

FIGS. **4**A-**4**G illustrate how adjacent leaflets can be stitched together in prosthetic heart valves provided herein.

FIGS. **5**A-**5**C illustrate a cross stitch provided herein for connecting a seal to a braided stent in an exemplary prosthetic heart valve provided herein. FIG. **5**A shows a front view of a seal having apertures and stitch patterns used for securing the seal to the braided stent. FIG. **5**B depicts a close up view of a cross stitch and a portion of a circumferential stitch used for securing the seal to the braided stent. FIG. **5**C depicts a cross-sectional view showing the cross stitch and a portion of the circumferential stitch.

FIG. **6** depicts an apparatus that can be used to form a tubular seal provided herein.

FIGS. **7**A-**7**E depict exemplary tubular seals having a fabric positioned within a matrix that can be used in a prosthetic heart valve provided herein.

Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

Prosthetic heart valves provided herein can include a braided stent expandable member secured to a tubular seal using a plurality of cross stitches at a plurality of intersection points of wires of the braided stent. Stitching at intersection points (e.g., intersection points immediately adjacent to inflow crowns) as opposed to at inflow crowns can increase the strength of the attachment while also allowing for improved load transfer to the braided stent. Each stitch, which is described in further detail below, can be formed by passing two stitches of suture in orthogonal directions over the wire intersections, passing through the fabric strip in four locations. Each cross stitch can be individual knotted. In some cases, the cross stitches do not pass through any of the leaflets. The cross stitch can be repeated at many intersections circumferentially around an inflow end of a prosthetic heart valve provided herein until the entire length of the tubular seal is securely attached.

FIGS. **1**A and **1**B illustrate an exemplary prosthetic heart valve **100** provided herein. FIGS. **1**C-**1**H depict how prosthetic heart valve **100** is deployed. FIG. **1**A is a perspective view of prosthetic heart valve **100** connected to a deployment device **190**. FIG. **1**B is a side view of prosthetic heart valve **100**. As shown, prosthetic heart valve **100** includes an expandable member **110**, three leaflets **200**, three anchor elements **120** that secure sleeve portions **216** of leaflets **200** to expandable member **110**, and a tubular seal **130** secured around a blood inflow end of prosthetic heart valve **100**. Anchor elements **120** can include post leg compression elements **122** and clamping support structures **126** adapted to provide support along opposite sides of the sleeve portions **216**. Expandable member **110** in FIGS. **1**A-**1**D is a braided stent, which is adapted to transition between a restricted state having a smaller diameter and an expanded state having a larger diameter. Expandable member **110** can be self-expanding, mechanically expanded, or a combination thereof.

FIGS. **1**C-**1**H depict how an exemplary heart valve delivery system can deliver the prosthetic heart valve provided herein. As shown in FIGS. **1**C-**1**H, prosthetic heart valve **100** can be deployed using a heart valve delivery system **180**. System **180** can include a sheath **182** for retaining the prosthetic heart valve **100** with the expandable member **110** in a restricted state. Within sheath **182**, anchor elements **120** (FIGS. **1**A and **1**B) can be connected to pushing prongs **192** and a pull line **194** can be connected to a nose cap **196**, or end cap, which is positioned at the end of the sheath **182**. As shown in FIG. **1**A, the pull line **194** can extend through expandable member **110** and through the valve opening between the leaflets **200**. As shown by FIGS. **1**D-**1**H, once a distal end of sheath **182** is delivered through the circulatory system to an appropriate location (e.g., within the heart), prosthetic heart valve **100** can be deployed. By advancing pushing prongs **192** and pull line **194** relative to sheath **182**, prosthetic heart valve **100** can be pushed out of the sheath **182**. In some cases, expandable member **110** can self-expand upon exiting sheath **182**. In some cases, expandable member **110** can self-expand to a first intermediate diameter, and system **180** can mechanically expand expandable member **110** to a larger deployment diameter. For example, anchor elements **120** can include a locking mechanism to clip a portion of expandable member when the expandable member **110** is expanded to a predetermined locking diameter. In some cases, system **180** can mechanically expand expandable member **110** to a predetermined locking diameter. In some cases, system **180** can compress expandable member **110** between pushing prongs **192** and nose cap **196** by moving pull line **194** relative to pushing prongs **192**. The predetermined locking diameter can be adapted to set the diameter of the prosthetic heart valve **100** during implantation. After prosthetic heart valve **100** is set, system **180** can move pull line **194** and nose cap **196** relative to pushing prongs **192** to move the end cap through the opening between leaflets **200** in prosthetic heart valve **100**. Pushing prongs **192** can then be retracted from anchor elements **120** and retracted into sheath **182**. In some cases, pushing prongs **192** can include a shape member material adapted to help radially expand expandable member **110** as the expandable member **110** exits sheath **182**. A control handle **188** can be used to control the relative movements of sheath **182**, pushing prongs **192**, and pull wire **194**. Prosthetic heart valves provided herein can be adapted to mitigate damage that might otherwise occur to valves during delivery and implantation.

In some cases, one or more radiopaque markers can be secured to prosthetic heart valves provided herein. As shown in FIGS. **1**A and **1**B, expandable member **110** includes a radiopaque marker **112**. Any suitable radiopaque material (such as platinum, palladium, gold, tantalum, or alloys thereof) can be used as the radiopaque material in radiopaque marker **112**. One or more radiopaque markers can be used with an imaging system to help a physician ensure that a valve is set in an appropriate location. In some cases, prosthetic heart valves provided herein include at least three radiopaque markers.

As shown in FIG. **1**A, prosthetic heart valve **100** can include a plurality of leaflets **200**. In some cases, as shown, prosthetic heart valve **100** includes three leaflets **200**. In some cases, prosthetic heart valves provided herein can have any suitable number of leaflets, such as two, three, four, five, or more leaflets. In some cases, leaflets **200** are secured to one another. In some cases, leaflets **200** can be secured to one another via a plurality of sutures. Leaflets **200** can be sutured along side edges of a body portion of each leaflet. In some cases, prosthetic heart valves provide herein can include a single line of sutures, which can be adapted to minimize leaks, minimize the width of a seam, and/or minimize the profile of a replacement heart valve during percutaneous insertion. In some cases, prosthetic heart valves provide herein can include multiple lines of sutures.

Expandable member **110** can have any suitable structure, arrangement, or material. In some cases, expandable member **110** can include a braided wire stent. For example, U.S. Publication Number 2005/0143809, titled, "Methods and Apparatus for Endovascularly Replacing a Heart Valve," and filed on Nov. 5, 2004, which is herein incorporated by reference for its disclosure of possible structures and materials for a braided wire stent, discloses a braided wire stent. In some cases, expandable member **110** includes a shape memory material (e.g., a nickel-titanium alloy or a cobalt-chromium alloy).

Referring to FIGS. **2**A-**2**C, a leaflet **200** can include a body portion **214** and sleeve portions **216**. In some cases, the body portion **214** has a bottom edge **222**, a first side edge **226**, a second side edge **228**, and a free edge **224**. Leaflet **200**

further includes a front (i.e., the side that blood flows toward), a back (i.e., the side that blood flows away from), a first side adjacent to the first side edge **226**, and a second side adjacent to the second side edge **228**. In some cases, the front of the leaflet **200** has a different texture than the back. In some cases, for example, the back of the leaflet may be prone to calcium build due to its cusp-shaped surface, therefore it can be beneficial to have a textured surface on the back of the leaflet to mitigate valve calcification issues. In some cases, however, having the back with a non-textured surface can mitigate calcification issues. In some cases, the leaflet **200** is made from tissue obtained from an animal, e.g., a pig or a cow. In some cases, leaflet **200** is made from bovine pericardium. Leaflets **200** can also be made from a synthetic material. Leaflets **200** can be assembled into a heart valve by aligning the opposite side regions of at least two adjacent leaflets **200** and stitching the leaflets **200** together along stitch line **246**, as shown in FIG. **2**C.

As shown in FIGS. **2**A-**2**C, a prosthetic heart valve can include at least one leaflet **200** having a body portion **214** and two opposite sleeve portions **216**. The body portion **214** can be defined by two side edges **226**, **228** adjacent each sleeve portion **216**. The at least one leaflet **200** can define at least one notch **232**, **234** between at least one of the two side edges **226**, **228** and the adjacent sleeve portion **216**. In other words, each notch **232**, **234** can be located along the side edges **228**, **226** at a location that is adjacent to the sleeve portions **216**, at an armpit of the leaflet **200**, as depicted in FIGS. **2**A and **2**B. In some cases, leaflet **200** can define a notch **232**, **234** generally along the side edges **228**, **226**. In some cases, a notch **232**, **234** can be defined along the sleeve portion **216**. In some cases, multiple notches **232**, **234** can be located along the sleeve portion **216** or one of the side edges **228**, **226**, and/or at the armpit of the leaflet **200**.

As shown in FIGS. **2**A and **2**B, the body portion **214** of the leaflet can have a conical frustum shape defined by a bottom edge **222**, the first side edge **226**, the second side edge **228**, and a free edge **224**. In some cases, other suitable shapes for the body portion can be contemplated, for example, a generally square, rectangular, triangular or trapezoidal shaped body portion.

The sleeve portions, as shown in FIGS. **2**A-**2**C, can extend outwardly from the body portion of the leaflet **200**. Each sleeve portion may be angled away from free edge of the body portion. Sleeve portions can be generally rectangular-shaped extensions with lateral ends. In some cases, the sleeve portions can have rounded ends.

Still referring to FIGS. **2**A-**2**C, notches **232**, **234** can be generally U-shaped. Other suitable notch shapes can include, but are not limited to, a V-shaped, Z-shaped, rectangular-shaped and an oval-shaped notch. Notches can also have rounded edges to smooth the transition between a notch and the side edges **228**, **226** of the leaflet **200**. Notches **232**, **234** can have a length dimension that can range from about 0.02 inches to about 0.20 inches (or from about 0.5 millimeters (mm) to about 4 mm).

Referring to FIG. **2**C, notches **232**, **234** can be shaped and sized to accommodate attachment of post leg compression elements **122**. Post leg compression elements **122** can be a part of anchor elements **120** (shown in FIGS. **1**A and **1**B) that compress and restrain sleeve portions **216** along the same line as the stitch line **246**. A suture **258** can be used to apply an appropriate and consistent compressive force between the post leg compression elements **122** in order to prevent leakage through sleeve portions **216** of the leaflets **200**. Sutures that pierce the body portion **214** at or near the armpit of the leaflet, however, can pull, stretch and abrade the surrounding adjacent tissue, creating stress concentrations at or near the armpit of the leaflet. Stress concentrators can result in tears forming in the leaflet material. Using notches **232** and **234** and post leg compression elements **122**, however, can minimize potential heart valve tearing caused by sutures at or near the armpit location. Notches **232**, **234** can be positioned proximate to the post leg compression elements near the armpit of the leaflet, e.g., between at least one of the two side edges **226**, **228** and the adjacent sleeve portion **216**, to create enlarged openings that suture **258** can pass therethrough without pulling or stretching the adjacent tissue. Accordingly, a notched leaflet **200** can improve valve opening capabilities and the reliability of prosthetic heart valves provided herein.

FIG. **3** illustrates another exemplary leaflet, which can be used in prosthetic heart valves provided herein. As shown in FIG. **3**, leaflet **300** can include a body portion **314** and at least two opposite sleeve portions **316**. The body portion **314** can be defined by at least two side edges **326**, **328** adjacent each sleeve portion **316**. Leaflet **300** can define two apertures **332** and **334**. Each aperture **332**, **334** can be positioned adjacent the side edges **326**, **328** and an adjacent sleeve portion **316**. Each aperture **332**, **334** can be adapted to secure one leaflet to an adjacent leaflet.

In some cases, the body portion **314** has a bottom edge **322**, a first side edge **326**, a second side edge **328**, and a free edge **324**. Leaflet **300** further includes a front, a back, a first side adjacent to the first side edge **326**, and a second side adjacent to the second side edge **328**. In some cases, the front of the leaflet **300** has a different texture than the back. In some cases, this occurs where the leaflet **300** is made from pig, cow, or other natural animal tissue. In some cases, leaflet **300** is made from bovine pericardium. Leaflets **300** can also be made from a synthetic material. Leaflets **300** can be assembled into a heart valve by aligning the opposite side regions of at least two adjacent leaflets **300** and stitching the leaflets **300** together along stitch line **246**, as shown in FIG. **2**C.

As shown in FIG. **3**, leaflet **300** defines apertures **332** and **334** adjacent the side edges **328**, **326** and adjacent the sleeve portions **316**. Apertures **332** and **334** can be generally circular in shape. Other suitable aperture shapes can include, for example, a rectangular, an oval, a triangular, or a diamond shape. In some cases, apertures **332**, **334** can have a length dimension or a diameter from about 0.02 inches to about 0.20 inches (or from about 0.5 mm to about 4 mm). In some cases, one or more apertures **332**, **334** can be located in the side edges **328**, **326** and/or the sleeve portions **316** of the leaflet **300**. In some cases, multiple apertures can be located in a region that is adjacent to the side edges **328**, **326** and the sleeve portions **316**.

Apertures **332**, **334** in the leaflets **300** can allow one leaflet to be secured to an adjacent leaflet. Similar to the notches discussed above, apertures **332** and **334** can be shaped and sized to accommodate attachment of post leg compression elements **122**. Referring back to FIGS. **1**A and **1**B, post leg compression elements **122** can be a part of anchor elements **120** that compress and restrain sleeve portions **216** along the same line as the stitch line **246**. A suture **258** can be used to apply an appropriate and consistent compressive force between the post leg compression elements **122** in order to prevent leakage through sleeve portions **216** of the leaflets **200**. As already discussed herein, sutures that pierce the body portion **214** at or near the armpit of the leaflet can create stress concentrations at or near the armpit of the leaflet that may result in tearing. Apertures **332** and **334** and post leg compression elements **122**, however,

can minimize this potential tearing caused by sutures near the armpit location. Apertures **332**, **334** can be positioned proximate to the post leg compression elements near the armpit location to create enlarged openings that suture **258** can pass therethrough without pulling or stretching the adjacent tissue. Accordingly, leaflets **300** used in prosthetic heart valves provided herein can improve the reliability of prosthetic heart valves provided herein.

FIGS. **4**A-**4**G depict how leaflets **200** can be connected (or jointed) with an improved stitch discussed herein. As shown, stitch **446** can be a single continuous line stitch traveling along a stitch line in a forward direction and back in a reverse direction. In some cases, stitch **446** can run along a leaflet from a bottom edge to a side edge of the leaflet (e.g., bottom edge **222** to side edge **226** of leaflet **200** in FIG. **2**A-**2**B). In some cases, stitch **446** can run from a side edge to a notch of a leaflet (e.g., side edge **226** to notch **234** of leaflet **200** in FIG. **2**A-**2**B).

As shown in FIGS. **4**D-**4**G, stitch **446** can include a plurality of perpendicular loop segments **434** extending through an aperture in the two leaflets, around outer side edges of the two attached leaflets, and back through the aperture. Stitch **446** can include a plurality of parallel segments **436** extending between adjacent apertures along the stitch line. Stitch **446** can include two perpendicular loop segments **434** extending through apertures formed in the stitch line. In some cases, a first perpendicular loop segment **434** for a first aperture in the stitch line is formed when the stitch is formed in the forward direction and a second perpendicular loop segment **434** for the first aperture is formed in the reverse direction. In some cases, parallel segments **436** made in a forward direction alternate between opposite sides of the two leaflets between each aperture in the stitch line. In some cases, parallel segments **436** made in a reverse direction are formed on an opposite side of the two leaflets from parallel segments **436** made in a forward direction. In some cases, opposite parallel segments **436** made in the forward and reverse directions can provide a continuous compressive force along the entire length of the stitch line. Perpendicular loop segments **434** can provide compressive force to reinforce a seal formed between the two leaflets along the stitch line.

Stitch **446** can include any appropriate number of perpendicular loop segments formed through any appropriate number of apertures. As shown, stitch **446** includes six perpendicular loop segments formed through six apertures (two perpendicular loop segments per aperture). In some cases, stitch **446** can include up to twelve perpendicular loop segments formed through six or more apertures. In some cases, a stitch connecting side edge segments of leaflets can be formed using between 3 and 20 apertures and include between 3 and 40 perpendicular loop segments. In some cases, apertures can be positioned from about 0.008 inches to about 0.4 inches apart (about 0.2 mm to about 10 mm apart). In some cases, apertures can be positioned from about 0.008 inches to about 0.4 inches (about 0.2 mm to about 10 mm) away from the side edges of the leaflets.

Stitch **446** can be formed in a process depicted in FIGS. **4**A-**4**G. As shown in FIG. **4**A, a thread needle **410** can be passed through aligned leaflet side edges **226***a* and **226***b* to create a first aperture at a location near bottom edges **222**, e.g., a location approximately 1 mm from the bottom edges **222**. The leaflet side edges **226***a* and **226***b* can be retained in a desired configuration by clamping the leaflets between clamp sides **422** and **424**. Needle **410** pulls a leading end **431** of a thread **432** through the first aperture. As shown in FIG. **4**B, needle **410** can then form a second aperture adjacent to the first aperture along the stitch line (towards the leaflet sleeve portion) about 0.5 mm away from the first aperture to pull leading end **431** of thread **432** through the second aperture to form a first parallel segment. As shown in FIG. **4**C, a perpendicular loop segment **434** can be made by guiding needle **410** around the leaflet side edges and re-enter the second aperture from a backside. Thread **432** can be pulled through the second aperture until it sits firmly against the leaflet material (e.g., leaflet pericardium tissue). FIG. **4**D shows a second parallel segment, which can be made by pushing needle **410** through leaflet tissue along the stitch line to form a third aperture approximately 1 mm from the second aperture (towards the sleeve segments of the leaflet). As shown in FIG. **4**E, a second perpendicular loop segment **434** can be formed by again having needle **410** loop around the leaflet side edges and reenter the third aperture through the backside. This is repeated up to notch **234** to form a total of six parallel segments **436** and six perpendicular loop segments **434** in a forward direction, as shown in FIG. **4**F. The stitch pattern can then be repeated in a reverse direction towards the bottom edges **222** of the leaflets through the previously formed apertures. Accordingly, each aperture can include two perpendicular loop segments **434** and parallel segments on the opposite sides can be formed from the parallel segments that were created in the forward direction, as shown in FIG. **4**G. The method and stitches depicted in FIGS. **4**A-**4**G can be applicable to leaflets **200**, **300** discussed herein.

Stitch **446** and other stitches provided herein can improve the reliability of a seal formed along a stitch line, create fewer apertures through the leaflets, and simplify the stitching operation. Having fewer apertures can help minimize the occurrence of blood leakage through the apertures. The single continuous line of stitch **446** using a single row of apertures can minimize a width of a side edge portion needed to form a continuous seal along the side edges of the leaflets, thus providing a reduced restricted profile for prosthetic heart valves provided herein. For example, U.S. Pat. No. 8,778,020 describes a variety of ways that leaflets can be sutured together using combinations of whip stitches and running stitches, but these stitches require additional apertures and multiple lines. Perpendicular loop segments **434** can stitch a plurality of leaflets together, similar to the whip stitches discussed in U.S. Pat. No. 8,778,020. Parallel segments **436** can secure valve leaflets to one another, similar to the running stitches discussed in U.S. Pat. No. 8,778,020. Although stitch **446** can provide an improved attachment between side edges of leaflets in prosthetic heart valves provided herein, some embodiments of prosthetic heart valves provided herein can use other stitch patterns, such as those described in U.S. Pat. No. 8,778,020, which is hereby incorporated by reference.

Important characteristics of the thread can include, but are not limited to, tensile strength, abrasion resistance and creep rupture resistance characteristics that allow the device to be delivered and implanted into a human anatomy. The thread used for suturing together portions of the heart valve, e.g., sides edges of the leaflets, can be composed of biocompatible materials that include, but are not limited to, polyethylenes such as ultra high molecular weight polyethylene (UHMWPE), polyesters (PET), and combinations thereof.

Referring back to FIGS. **1**A and **1**B, prosthetic heart valve **100** can include a tubular seal **130**. Tubular seal **130** can be secured to bottom edges **222** (FIG. **2**A) of the body portion **214** of at least one leaflet **200** by a circumferential running stitch **134** within prosthetic heart valve **100**. Tubular seal **130** can be secured to expandable tubular member **110** by

fasteners **136** and extended around the outside of expandable tubular member **110** to provide a seal that minimizes blood leakage around the leaflets **200** of an implanted prosthetic heart valve **100**. The structure and materials of tubular seal **130** are discussed below in reference to FIGS. **6** and **7**A-**7**E.

Referring to FIGS. **5**A-**5**C, an improved tubular seal stitching pattern can include a cross stitch **132** between tubular seal **130** and expandable member **110**. FIGS. **5**A-**5**C illustrate how the tubular seal **130** can be secured to the expandable member **110**, e.g., a braided stent, by a plurality of cross stitches connecting the tubular seal **130** to a pair of overlapping wire members of the braided stent. As shown in FIGS. **1**A, **1**B and **5**A-**5**C, expandable member **110** can be a braided stent including one or more wires having a first set of segments **114** extending helically in a first direction and a second set of segments **116** extending helically in a second direction such that the first set of segments **114** cross the second set of segments **116** at intersection points **118**. As shown, one or more wires can have inflow crowns **115** at an end of the braided stent where the wires transition from first segments **114** to second segments **116**. In some cases, cross stitches **132** secure tubular seal **130** at an intersection **118** to two crossing segments **114**, **116** of the braided stent. A separate circumferential running stitch **134** can be inserted into preformed apertures **133** to secure the adaptive seal to bottom edges **222** of leaflets **200** shown in FIGS. **2**A and **2**C. Cross-stitches around the intersections **118** can increase the strength of an attachment of tubular seal **130** to the expandable member **110** while also allowing for improved load transfer to the expandable member **110**. In some cases, the cross stitches secure tubular seal **130** at intersections **118** located immediately above (proximal) the inflow crowns **115**. Cross stitches **132** can be formed by passing two stitches **132***a*, **132***b* of a suture in orthogonal directions over the intersections **118** and through the tubular seal **130**. In some cases, preformed apertures **131** for cross stitch **132** can be formed in the tubular seal **130**. In some cases, a portion of the tubular seal **130** that is sutured by cross stitch **132** includes an internal fabric, such as those discussed below. Each cross stitch **132** can be knotted independently. As shown in FIG. **5**C, cross stitches **132** each include a separate knot **137**. Additionally, cross stitches **132** can be arranged to not pass through leaflets **200**. Cross stitches **132** can be repeated at a plurality of intersections **118** (FIG. **5**A) circumferentially around an inflow end of a prosthetic heart valve provided herein such that an entire circumference of tubular seal **130** is securely attached. In some cases, each intersection **118** immediately adjacent to inflow crowns **115** is sutured to tubular seal **130** via a cross stitch provided herein. The tubular seal stitching pattern provided herein can increase the strength of the attachment between the tubular seal **130** and the expandable member **110** while also allowing for improved load transfer to the expandable member **110** through the use of the plurality of cross stitches.

Tubular seal **130** can have any suitable structure. In some cases, tubular seal **130** can include an elastic material. In some cases, tubular seal **130** can include one or more layers of an elastomeric polymer. In some cases, tubular seal **130** can include a polycarbonate, polyurethane, silicone, polytetrafluoroethylene (PTFE), or a combination thereof. Other suitable materials include, but are not limited to, natural and synthetic rubbers, including cis-1,4-polyisoprene rubber, styrene/butadierie copolymers, polybutadiene rubber, styrene/isoprene/butadiene rubber, butyl rubber, halobutyl rubber; polyurethane elastomers, including elastomers based on both aromatic and aliphatic isocyanates; flexible polyolefins, including flexible polyethylene and polypropylene homopolymers and copolymers; styrenic thermoplastic elastomers; polyamide elastomers; polyamide-ether elastomers; ester-ether or ester-ester elastomers; flexible ionomers; thermoplastic vulcanizates; flexible poly(vinyl chloride) homopolymers and copolymers; flexible acrylic polymers; and blends and alloys of these, such as poly(vinyl chloride) alloys like poly(vinyl chloride)-polyurethane alloys. In some cases, tubular seal **130** can include an aliphatic polycarbonate-based thermoplastic urethane. In some cases, tubular seal **130** can include an elastomeric polymer having a hardness ranging from 3.07 MPa to 9.9 MPa, or a durometer ranging from 75 Shore A to 75 Shore D using ASTM standard D2240 in force on Jan. 1, 2014. In some cases, tubular seal **130** can include a polymeric material having the mechanical properties shown in Table I below. Notably, all of the listed ASTM standards refers to the standard in force on Jan. 1, 2014.

TABLE I

		ASTM Standard
Durometer Range Available	75 Shore A-75 Shore D	D2240
Specific Gravity	1.10-1.14	D792
Melt Flow	2-26 g/10 min(205° C./3.26 kg)	D1238

	MECHANICAL PROPERTY RANGES			ASTM Standard
Durometer	75A-B20	55D	75D	75D
Ultimate Tensile Strength (psi)	400-9000	5000-10000	3000-8000	D638
Tensile (psi)				
@50% elongation	350-650	1500-1800	3000-8000	D638
@100% elongation	550-850	1800-2200	3000-8000	D638
@200% elongation	600-1200	2800-4200		D638
@300% elongation	1200-2000	4200-10000		D630
Ultimate Elongation (%)	350-750	200-400	100-300	D638

In some cases, referring back to FIG. **1**A, tubular seal **130** can include attachment structures to improve the attachment of the tubular seal **130** to leaflets **200** and/or expandable member **110**.

In some cases, as shown in FIG. **7**A, a tubular seal **730** can include an inflow end section **740** and an outflow end section **750**. The inflow end section **740** can include a fabric embedded within elastomeric material and the outflow end section **750** can include a plurality of grommets **732**. The fabric of inflow end section **740** can be a woven material. In some cases, the fabric can have warp threads and/or weft

threads. The fabric is composed of fibers having an average thread diameter from about 0.00002 inches to about 0.002 inches (or from about 0.5 microns to about 50 microns), more preferably from about 0.0008 inches to about 0.002 inches (or from about 20 micron to about 40 microns). In some cases, more preferably, the fabric is composed of fibers having a thread diameter of about 0.0011 inches (about 27 microns).

In some cases, the fabric can include non-elastomeric fibers. Suitable non-elastomeric fiber materials include, but are not limited to, polyolefins, polyesters such as PES 38/31 manufactured by SaatiTech, and polyamides. More particularly, the polyolefins may be, for example, one or more of polyethylene, polypropylene, polybutene, ethylene copolymers, propylene copolymers, and butene copolymers. Because the fabric can include non-elastic fibers, inflow end section **740** and outflow end section **750** can have different overall elastic properties. In some cases, tubular seal **730** can be used as a tubular seal **130** of prosthetic heart valve **100**, as previously shown in FIG. **1**A. In some cases, tubular seal **730** can be used in other prosthetic heart valves provided herein.

As shown in FIGS. **7**A-**7**D, an interface **753** between the inflow end section **740** and the outflow end section **750** is non-linear due to a non-linear edge of fabric within the inflow end section **740**. As shown in FIG. **7**A, the non-linear edge can be sinusoidal **753**. In some cases, as shown in FIGS. **7**C-**7**D, the non-linear edge can be a zigzagged edge **754**, a stepped edge **755**, or a scalloped edge **756**.

In some cases, inflow end section **740** can be thicker than outflow end section because of the presence of a fabric within inflow end section **740**, **750**. In some cases, inflow end section **740** can have a thickness of about 0.0028 inches (about 70 microns) and the outflow end section **750** can have a thickness of about 0.0020 inches (about 50 microns). Other suitable thicknesses for the inflow end section include thicknesses ranging from about 0.0020 inches to about 0.0035 inches (about 50 microns to about 90 microns), or more preferably, from about 0.0025 inches to about 0.0031 inches (about 60 microns to about 80 microns). Suitable thicknesses for the outflow end section include thicknesses ranging from about 0.0011 inches to about 0.0028 inches (about 30 microns to about 70 microns), or more preferably, from about 0.0016 inches to about 0.0023 inches (about 40 microns to about 60 microns). In some cases, suitable thickness ratios of the inflow end section relative to the outflow end section can range from 1:1 to 1.2:1, from 1.2:1 to 1.4:1, from 1.4:1 to 1.5:1, and from 1.5:1 to 2:1. A non-linear edge can providing a non-linear interface between the inflow end section **740** and the outflow end section **750**. A prosthetic heart valve with the non-linear interface may have an increased overall diameter that tapers more gradually when compared to a prosthetic heart valve that has a linear interface. The non-linear edge of the fabric can also gradually transition the change in elastic properties between the outflow end section **750** and the inflow end section **740**, mitigating the formation of stress concentrators along the interface **753** that can cause tearing in the tubular member. Additionally, the shape of non-linear interface **753** can limit the propagation of tears.

In some cases, the fabric can be arranged in the inflow end section **740** to allow for the fabric within inflow end section **740** to stretch in axial and/or radial directions to allow the tubular seal to stretch along with an expandable member during implantation. When the fabric does not allow the tubular seal to adequately stretch, the seal can cause non-uniform crimping during manufacturing or damage the expandable member during device deployment. In some cases, a woven fabric can be arranged to have the warp and the waft extend in directions oblique to the axis of the tubular seal. This can allow the fabric to flex in radial and/or axial directions relative to the axis of the tubular seal, but limit the fabric from stretching in a direction oblique to the axis. In some cases, both the warp and the waft can extend at an angle between 30 degrees and 60 degrees with the axis of the tubular seal. In some cases, both the warp and the waft can extend at an angle between 5 degrees and 70 degrees with the axis of the tubular seal. In some cases, the warp and waft can be arranged within the tubular member **730** to form an angle of about 45 degrees with the axis of the tubular seal. In some cases, the fabric can be a knit fabric arranged to allow for a predetermined amount of stretch in the axial and/or radial directions. Limiting the fabric within inflow end section **740** from stretching in a direction oblique to the axis can prevent the fabric from bunching and minimize non-uniform crimping during manufacturing.

Additional exemplary tubular seals including a fabric and grommets are described in U.S. Patent Application No. 2013/0090729, which is hereby incorporated by reference in its entirety. For example, U.S. Pat. No. 8,778,020 describes a seal that includes a multilayer, cylindrical seal body having projections alternating with recesses along the proximal edge of the seal body with proximal reinforcing grommets and a distal reinforcing band, which may be formed from a woven or nonwoven fabric and either incorporated within the interior of the multilayer seal body or adhered to the surface thereof.

In some cases, tubular seals described in U.S. Patent Application No. 2013/0090729 can be modified to include a fabric arrangement that allows a seal to stretch in axial and/or radial directions. In some cases, elastomeric materials provided herein can be incorporated into the tubular seals disclosed in U.S. Patent Application No. 2013/0090729. In some cases, the tubular seals described in U.S. Patent Application No. 2013/0090729 can be modified to include the non-linear interface **753** provided herein.

Referring back to FIG. **7**A, tubular seal **730** can be created by producing one or more layers of elastomeric polymer, applying the fabric and grommets **732** to the one or more layers of elastomeric polymer, and overcoating the fabric and grommets **732** with one or more additional layers of elastomeric material. In some cases, different layers can have different elastomeric properties. In some cases, tubular seals (e.g., **130**, **730**, or **760**) can include a radially innermost layer including at least one elastomeric polymer, e.g., a polycarbonate and a polyurethane; a radially outermost layer including at least one elastomeric polymer, e.g., a polycarbonate and a polyurethane; and at least one inner layer disposed between the radially outermost layer and a radially innermost layer. In some cases, the modulus of elasticity of the innermost layer is less than the modulus of elasticity of the radially innermost outer layer and the modulus of elasticity of the radially outermost outer layer. In some cases, the elongation to break of the inner layer is greater than the elongation to break of the radially innermost outer layer and the elongation to break of the radially outermost outer layer. Although the radially innermost outer layer and the radially outermost outer layer have been depicted as including the same material, it will be appreciated that they may be compositionally the same or different.

The multilayer tubular seals provided herein (e.g., **130**, **730**, **760**) may be formed in a variety of ways. In some cases, multilayer tubular seals provided herein may be formed by successive applications of a polymer solution to an appro-

priately shaped mandrel, such as that illustrated in FIG. **6**. Following a careful cleaning of the mandrel **600**, the mandrel may be mounted to an appropriate holding fixture in a spray booth. A first coating composition including a carrier and at least one polymer may be applied to the mandrel **600** and subsequently dried to form a first coated mandrel. In some cases, the first coating composition includes one or more elastomeric polymers, e.g, polycarbonate and/or a polyurethane, and a volatile carrier. The coating composition may be applied as a single layer or multiple layers to achieve the desired dried coating thickness. The grommets **732** (FIG. **7**A) and the fabric may be positioned on the first coated mandrel by inserting locating pins **620** in apertures **610** in the tapered mandrel **600** which align with corresponding perforations **30** provided in the grommets **32**, **34**, **36** and the fabric **40**. In FIG. **6**, only one pin **620** has been illustrated for clarity. In some instances, it may be desirable to secure the plurality of grommets **732** and the fabric to the mandrel or to an underlying coating layer by applying a drop of a first coating composition, or other adhesive composition, to each item to ensure that it remains properly positioned during subsequent processing. The fabric can be cut to a suitable shape having a non-linear edge using any suitable method. In some cases, the fabric can be die cut. In some cases, the fabric can be cut with a blade. In some cases, the fabric can be cut using a femtosecond laser. In some cases, a femtosecond laser cut fabric mitigate the chances of forming stress concentrators along the edge of the fabric.

A second coating composition including a carrier and at least one polymer may be applied to the first coated mandrel, the fabric, and the plurality of grommets. In some cases, the second coating composition includes one or more elastomeric polymers, e.g, polycarbonate and/or a polyurethane, and a volatile carrier. The carrier of the second coating composition may be removed, thereby forming a second coated mandrel. The second coating composition may be applied as a single layer or as multiple layers to achieve the desired dried coating thickness. In some cases, the second coating composition may be different from the first coating composition. In some cases, the second coating composition may be composed of the same material as the first coating composition.

In some cases, a third coating composition including a carrier and at least one polymer may be applied to the second coated mandrel. In some cases, the third coating composition includes one or more elastomeric polymers, e.g, polycarbonate and/or a polyurethane, and a volatile carrier. The carrier of the third coating composition may be removed thereby forming a tubular seal precursor. The third coating composition may be applied as a single layer or as multiple layers to achieve the desired dried coating thickness. In some cases, the third coating composition may be different from the first coating composition. In some cases, the third coating composition may be the same as the first coating composition. In some cases, the third coating composition may be different from the second coating composition. In some cases, the third coating composition may be the same as the second coating composition. Following removal of the carrier from the third coating composition, the tubular seal precursor may be inspected to ensure that it is fully formed and meets dimensional specifications, such as a thickness specification. In some cases, a suitable thickness for the tubular seal precursor can range from about 0.001 inches to about 0.0030 inches (about 30 microns to about 75 microns) or from about 0.002 inches to about 0.0047 inches (about 50 microns to about 120 microns). Other suitable thicknesses for the tubular seal precursor include a range from about 0.0008 inches to about 0.002 inches (about 20 microns to about 40 microns), about 0.001 inches to about 0.002 inches (about 30 microns to about 50 microns), about 0.002 inches to about 0.0029 inches (about 50 microns to about 75 microns), about 0.002 inches to about 0.004 inches (about 50 microns to about 100 microns), about 0.004 inches to about 0.0047 inches (about 100 microns to about 120 microns), about 0.004 inches to about 0.0059 inches (about 100 microns to about 150 microns), about 0.0059 inches to about 0.0079 inches (about 150 microns to about 200 microns), as well as any thickness value within any of the listed ranges.

In some cases, the tubular seal precursor may be inspected to ensure that it meets certain functional specifications, e.g., tensile and frictional specifications. The tubular seal precursor may then be trimmed by laser cutting, or blade cutting, to conform to dimensional specifications and removed from the tapered seal-forming mandrel as a formed tubular seal. In some cases, at least some preformed apertures for suturing tubular seal to expandable member **110** and/or leaflets **200** can be performed by laser cutting. In some cases, at least some of the grommets may be formed by a laser cutting operation performed on a tubular seal precursor. In some cases, grommets **732** of FIG. **7**A may be added to the multilayer, generally cylindrical seal, in a step not illustrated, as a proximal band. Subsequent laser cutting of the tubular seal precursor would then simultaneously form grommets **732** by removing the portions of the proximal band located between the projections.

In some cases, coating compositions may be selected to provide a relatively stiff dried polymer such as a dried polymer having a Shore D hardness of about 55, or a hardness of about 6.21 Megapascals (Mpa). In some cases, coating compositions may be selected to provide a relatively elastomeric dried polymer such as a dried polymer having a Shore A hardness of about 80, or a hardness of about 3.45 MPa. In some cases, the first and third dried polymer layers may have a Shore D hardness of 55, or a hardness of 6.21 MPa, and the second layer may have a Shore A hardness of 80, or a hardness of 3.45 MPa.

Although in some cases described above, three polymer layers were employed, it will be appreciated that a greater or lesser number of layers may be employed and that each of the three or more layers may include two or more sublayers. In some cases, the plurality of grommets and the fabric can be positioned between the first and second coating layers. In some cases, the plurality of grommets and the fabric can be positioned elsewhere within the tubular seal, e.g., within a layer, or on the radially innermost or radially outermost surface of the tubular seal.

The mandrel **600** of FIG. **6** includes a taper which results in a tubular seal having a slightly smaller diameter proximal end compared to the diameter of the distal end. In some cases, the diameter of the proximal end can include a diameter reduction of about 3% to about 30% as compared to the diameter of the distal end. The taper allows the tubular seal to be removed from the mandrel with relative ease upon completion of the fabrication process. The smaller proximal diameter of the tubular seal tends to cause the proximal projections to lie more firmly against an anchor element of the replacement heart valve. In some cases, the surface of the mandrel may be textured to create a tubular seal with a reduced contact area. In some cases, the mandrel can be textured using a bead blasting process. In combination with the selection of a relatively hard outer layer, a textured seal surface is believed to result in a lower friction surface.

As shown in FIG. 7E, a tubular seal **760** can include a woven or non-woven fabric embedded throughout a polymer or metal matrix structure. In some cases, at least one leaflet of the heart valve can be secured to the tubular seal in a portion of the tubular seal including the woven or non-woven fabric to minimize blood leakage between the tubular seal and the leaflets.

In some cases, the matrix structure can be made of elastomeric material. In some cases, tubular seal **760** can be made of the fabric alone. The fabric can include non-elastic fibers arranged to allow for the tubular seal **760** to stretch in axial and/or radial directions relative to the axis of the tubular seal **760**. In some cases, the non-elastic fibers can be arranged within the tubular member **760** to form an angle of about 45 degrees with the axis of the tubular seal. In some cases, the fabric can be a knit fabric arranged to allow for a predetermined amount of stretch in the axial and/or radial directions. In some cases, the fabric can be made of polymeric materials that include, but are not limited to, polyesters, polyolefins such as polyethylene and polypropylene, polyamides, nylons, and combinations thereof. In some cases, the fabric can have a thickness ranging from about 0.002 inches to about 0.003 inches (about 40 to about 80 microns). In some cases, the fabric can be woven such that spacings between individual fibers create openings in the fabric that together constitutes from about 20% to about 40% of a fabric surface.

A number of embodiments of the invention have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit and scope of the invention. Accordingly, other embodiments are within the scope of the following claims.

What is claimed is:

1. A prosthetic heart valve comprising:

an expandable member comprising one or more braided wires, the one or more braided wires comprising a first set of wire segments extended helically in a first direction and a second set of wire segments extended helically in a second direction such that each wire segment of the first set intersects a plurality of wire segments from the second set at a plurality of intersection points, wherein the one or more braided wires have crowns where the wire segments of the first set connect to wire segments of the second set;

a plurality of leaflets being secured within the expandable member; and

a tubular seal comprising an elastomeric material, the tubular seal having an inflow edge being secured to bottom inflow edges of the plurality of leaflets and to the expandable member by a plurality of sutures, characterized by the sutures comprising cross stitches formed around both a wire segment of the first set and a wire segment of the second set at one of the intersection points.

2. The prosthetic heart valve of claim **1**, wherein each cross stitch is an independently tied off stitch unconnected to other cross stitches.

3. The prosthetic heart valve of claim **1**, wherein each cross stitch is attached at an intersection point immediately adjacent a crown at an inflow side of the expandable member.

4. The prosthetic heart valve of claim **1**, wherein the plurality of leaflets are secured together along side edges thereof.

5. The prosthetic heart valve of claim **4**, wherein the plurality of leaflets each comprise two sleeve portions, wherein the sleeve portions are secured to the expandable member by a plurality of anchor elements.

6. The prosthetic heart valve of claim **1**, wherein the tubular seal comprises a plurality of non-elastic fibers retained within a matrix of the elastomeric material, the non-elastic fibers being arranged to allow the tubular seal to stretch in an axial or a radial direction.

7. The prosthetic heart valve of claim **6**, wherein the non-elastic fibers are part of a fabric.

8. The prosthetic heart valve of claim **7**, wherein the fabric has a thickness ranging from about 40 to about 80 microns.

9. The prosthetic heart valve of claim **7**, wherein the fabric is a woven fabric.

10. The prosthetic heart valve of claim **9**, wherein the woven fabric comprises fibers in a warp direction and fibers in a waft direction, wherein the fibers in both the warp direction and the waft direction are angled with respect to a central axis of the tubular seal.

11. The prosthetic heart valve of claim **10**, wherein the fibers in both the warp direction and the waft direct are angled at an angle between 5 degrees and 70 degrees with respect to the central axis of the tubular seal.

12. The prosthetic heart valve of claim **7**, wherein the fibers are made of polyester.

13. The prosthetic heart valve of claim **6**, wherein the non-elastic fibers are uniformly dispersed throughout the matrix.

14. The prosthetic heart valve of claim **1**, wherein the tubular seal has a substantially uniform thickness.

15. A prosthetic heart valve comprising:

an expandable member comprising one or more braided wires, the one or more braided wires comprising a first set of wire segments and a second set of wire segments such that each wire segment of the first set intersects a plurality of wire segments from the second set at a plurality of intersection points;

a plurality of leaflets being secured within the expandable member; and

a tubular seal comprising an elastomeric material, the tubular seal having an inflow edge being secured to bottom inflow edges of the plurality of leaflets and to the expandable member by a plurality of sutures, wherein the sutures comprise cross stitches formed around both a wire segment of the first set and a wire segment of the second set at one of the intersection points;

wherein the tubular seal comprises an outflow end region and an inflow end region, the inflow end region being a portion of the tubular seal comprising a fabric within a matrix of an elastomeric matrix, wherein the fabric has a non-linear edge defining an interface between the inflow end region and the outflow end region.

16. The prosthetic heart valve of claim **15**, wherein the non-linear edge of the fabric has a sinusoidal or scalloped shape.

17. The prosthetic heart valve of claim **15**, wherein the plurality of leaflets are secured to the tubular seal by a continuous circumferential running stitch.

18. The prosthetic heart valve of claim **15**, wherein the first set of wire segments extends helically in a first direction and a second set of wire segments extends helically in a second direction.

19. The prosthetic heart valve of claim **18**, wherein the one or more braided wires have crowns where the wire segments of the first set connect to wire segments of the second set.

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